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Thursday
August 19, 1999

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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.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–CE–10–AD; Amendment 39–11256; AD 99–17–08]

RIN 2120–AA64

Airworthiness Directives; Pilatus Aircraft Ltd. Models PC–12 and PC–12/45 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to certain Pilatus Aircraft Ltd. (Pilatus) Models PC–12 and PC–12/45 airplanes. This AD requires modifying the generator 2 excitation by removing certain diodes and installing a new 5-amp circuit breaker and suppression filter. This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Switzerland. The actions specified by this AD are intended to prevent damage to electrical components if the generator 2 is not switched off prior to engine shutdown and it overheats, which could result in loss of electrical power to certain critical airplane components.

DATES: Effective October 4, 1999. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 4, 1999.

ADDRESSES: Service information that applies to this AD may be obtained from Pilatus Aircraft Ltd., Customer Liaison Manager, CH–6371 Stans, Switzerland; telephone: +41 41 619 63 19; facsimile: +41 41 610 33 51. This information may also be examined at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 99–CE–10–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Roman T. Gabrys, Aerospace Engineer, FAA, Small Airplane Directorate, 1201 Walnut, suite 900, Kansas City, Missouri 64106; telephone: (816) 426–6932; facsimile: (816) 426–2169.

SUPPLEMENTARY INFORMATION:

Events Leading to the Issuance of This AD

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain Pilatus Models PC–12 and PC–12/45 airplanes was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on June 14, 1999 (64 FR 31758). The NPRM proposed to require modifying the generator 2 excitation by removing certain diodes and installing a new 5-amp circuit breaker and suppression filter. Accomplishment of the proposed action as specified in the NPRM would be required in accordance with Pilatus Service Bulletin No. 24–012, dated February 19, 1999.

The NPRM was the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Switzerland.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposed rule or the FAA's determination of the cost to the public.

The FAA's Determination

After careful review of all available information related to the subject presented above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed except for minor editorial corrections. The FAA has determined that these minor corrections will not change the meaning of the AD and will not add any additional burden upon the public than was already proposed.

Cost Impact

The FAA estimates that 69 airplanes in the U.S. registry will be affected by this AD, that it will take approximately 5 workhours per airplane to accomplish this action, and that the average labor rate is approximately $60 an hour. Parts will be provided at no cost to the owners/operators of the affected aircraft. Based on these figures, the total cost impact of this AD on U.S. operators is estimated to be $20,700, or $300 per airplane.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

99–17–08 Pilatus Aircraft Ltd.: Amendment 39–11256; Docket No. 99–CE–10–AD.

Applicability: Models PC–12 and PC–12/45 airplanes, manufacturer serial numbers (MSN) 101 through 260, certificated in any category.

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

Compliance: Required as indicated in the body of this AD, unless already accomplished.

To prevent damage to electrical components if the generator 2 is not switched off prior to engine shutdown and it overheats, which could result in loss of electrical power to certain critical airplane components, accomplish the following:

(a) Within the next 100 hours time-in-service (TIS) after the effective date of this AD, modify the generator 2 excitation by removing certain diodes and installing a new 5-amp circuit breaker and suppression filter. Perform these actions in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of Pilatus Service Bulletin No. 24–012, dated February 19, 1999.

Note 2: The affected airplanes incorporate one of the following generators:

—a BOSCH Generator 2, part number (P/N) 524.32.12.158. This generator is installed at the factory on Pilatus Models PC–12 and PC–12/45 airplanes beginning with MSN 231 and could be installed on airplanes with a MSN in the range of 101 through 230 by incorporating Pilatus Service Bulletin No. 24–010, dated September 28, 1998; or

—an ELECTRO SYSTEMS Generator 2, P/N 978.87.24.121, with Pilatus Service Bulletin No. 24–009 (installation of support bracket and cut-out relay) incorporated. This generator is installed at the factory on Pilatus Models PC–12 and PC–12/45 airplanes with a MSN in the range of 101 through 230. AD 99–06–17, Amendment 39–11081 (64 FR 13882, March 23, 1999), requires installing the support bracket and cut-out relay specified in Pilatus Service Bulletin No. 24–009, dated September 23, 1998, on Pilatus Models PC–12 and PC–12/45 airplanes with a MSN in the range of 101 through 180. This service bulletin is incorporated at the factory on airplanes with a MSN in the range of 181 through 230.

(b) As of the effective date of this AD, no person may install, on any affected airplane, a generator 2 that does not have the modification referenced in paragraph (a) of this AD incorporated.

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

(d) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate, 1201 Walnut, suite 900, Kansas City, Missouri 64106. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(e) Questions or technical information related to Pilatus Service Bulletin No. 24–012, dated February 19, 1999, should be directed to Pilatus Aircraft Ltd., Customer Liaison Manager, CH–6371 Stans, Switzerland; telephone: +41 41 619 63 19; facsimile: +41 41 610 33 51. This service information may be examined at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

(f) The modification required by this AD shall be done in accordance with Pilatus Service Bulletin No. 24–012, dated February 19, 1999. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Pilatus Aircraft Ltd., Customer Liaison Manager, CH–6371 Stans, Switzerland. Copies may be inspected at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in Swiss AD HB 99–143, dated February 19, 1999.

(g) This amendment becomes effective on October 4, 1999.

Issued in Kansas City, Missouri, on August 5, 1999.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–21016 Filed 8–18–99; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 211

[Release No. SAB 99]

Staff Accounting Bulletin No. 99

AGENCY: Securities and Exchange Commission.

ACTION: Publication of Staff Accounting Bulletin.

SUMMARY: This staff accounting bulletin expresses the views of the staff that exclusive reliance on certain quantitative benchmarks to assess materiality in preparing financial statements and performing audits of those financial statements is inappropriate; misstatements are not immaterial simply because they fall beneath a numerical threshold.

DATES: Effective August 12, 1999.

FOR FURTHER INFORMATION CONTACT: W. Scott Bayless, Associate Chief Accountant, or Robert E. Burns, Chief Counsel, Office of the Chief Accountant (202–942–4400), or David R. Fredrickson, Office of General Counsel (202–942–0900), Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–1103; electronic addresses: BaylessWS@sec.gov; BurnsR@sec.gov; FredricksonD@sec.gov.

SUPPLEMENTARY INFORMATION: The statements in the staff accounting bulletins are not rules or interpretations of the Commission, nor are they published as bearing the Commission's official approval. They represent interpretations and practices followed by the Division of Corporation Finance and the Office of the Chief Accountant in administering the disclosure requirements of the Federal securities laws.

Dated: August 12, 1999.

Margaret H. McFarland,

Deputy Secretary.

PART 211—[AMENDED]

Accordingly, Part 211 of Title 17 of the Code of Federal Regulations is amended by adding Staff Accounting Bulletin No. 99 to the table found in Subpart B.

Staff Accounting Bulletin No. 99

The staff hereby adds Section M to Topic 1 of the Staff Accounting Bulletin Series. Section M, entitled ''Materiality,'' provides guidance in applying materiality thresholds to the preparation of financial statements filed with the Commission and the performance of audits of those financial statements.

Staff Accounting Bulletins

Topic 1: Financial Statements

* * * * *

M. Materiality

1. Assessing Materiality

Facts: During the course of preparing or auditing year-end financial statements, financial management or the registrant's independent auditor becomes aware of misstatements in a registrant's financial statements. When combined, the misstatements result in a 4% overstatement of net income and a $.02 (4%) overstatement of earnings per share. Because no item in the registrant's consolidated financial statements is misstated by more than 5%, management and the independent auditor conclude that the deviation from generally accepted accounting principles (''GAAP'') is immaterial and that the accounting is permissible.[1]

Question: Each Statement of Financial Accounting Standards adopted by the Financial Accounting Standards Board (''FASB'') states, ''The provisions of this Statement need not be applied to immaterial items.'' In the staff's view, may a registrant or the auditor of its financial statements assume the immateriality of items that fall below a percentage threshold set by management or the auditor to determine whether amounts and items are material to the financial statements?

Interpretive Response: No. The staff is aware that certain registrants, over time, have developed quantitative thresholds as ''rules of thumb'' to assist in the preparation of their financial statements, and that auditors also have used these thresholds in their evaluation of whether items might be considered material to users of a registrant's financial statements. One rule of thumb in particular suggests that the misstatement or omission [2] of an item that falls under a 5% threshold is not material in the absence of particularly egregious circumstances, such as self-dealing or misappropriation by senior management. The staff reminds registrants and the auditors of their financial statements that exclusive reliance on this or any percentage or numerical threshold has no basis in the accounting literature or the law.

The use of a percentage as a numerical threshold, such as 5%, may provide the basis for a preliminary assumption that—without considering all relevant circumstances—a deviation of less than the specified percentage with respect to a particular item on the registrant's financial statements is unlikely to be material. The staff has no objection to such a ''rule of thumb'' as an initial step in assessing materiality. But quantifying, in percentage terms, the magnitude of a misstatement is only the beginning of an analysis of materiality; it cannot appropriately be used as a substitute for a full analysis of all relevant considerations.

Materiality concerns the significance of an item to users of a registrant's financial statements. A matter is ''material'' if there is a substantial likelihood that a reasonable person would consider it important. In its Statement of Financial Accounting Concepts No. 2, the FASB stated the essence of the concept of materiality as follows:

> The omission or misstatement of an item in a financial report is material if, in the light of surrounding circumstances, the magnitude of the item is such that it is probable that the judgment of a reasonable person relying upon the report would have been changed or influenced by the inclusion or correction of the item.[3]

This formulation in the accounting literature is in substance identical to the formulation used by the courts in interpreting the federal securities laws. The Supreme Court has held that a fact is material if there is—

> a substantial likelihood that the . . . fact would have been viewed by the reasonable investor as having significantly altered the ''total mix'' of information made available.[4]

Under the governing principles, an assessment of materiality requires that one views the facts in the context of the ''surrounding circumstances,'' as the accounting literature puts it, or the ''total mix'' of information, in the words of the Supreme Court. In the context of a misstatement of a financial statement item, while the ''total mix'' includes the size in numerical or percentage terms of the misstatement, it also includes the factual context in which the user of financial statements would view the financial statement item. The shorthand in the accounting and auditing literature for this analysis is that financial management and the auditor must consider both ''quantitative'' and ''qualitative'' factors in assessing an item's materiality.[5] Court decisions, Commission rules and enforcement actions, and accounting and auditing literature [6] have all considered ''qualitative'' factors in various contexts.

The FASB has long emphasized that materiality cannot be reduced to a numerical formula. In its Concepts Statement No. 2, the FASB noted that some had urged it to promulgate quantitative materiality guides for use in a variety of situations. The FASB rejected such an approach as representing only a ''minority view,'' stating—

> The predominant view is that materiality judgments can properly be made only by those who have all the facts. The Board's present position is that no general standards of materiality could be formulated to take into account all the considerations that enter into an experienced human judgment.[7]

The FASB noted that, in certain limited circumstances, the Commission and other authoritative bodies had issued quantitative materiality guidance, citing as examples guidelines ranging from one to ten percent with

[1] American Institute of Certified Public Accountants (''AICPA''), Codification of Statements on Auditing Standards (''AU'') § 312, ''Audit Risk and Materiality in Conducting an Audit,'' states that the auditor should consider audit risk and materiality both in (a) planning and setting the scope for the audit and (b) evaluating whether the financial statements taken as a whole are fairly presented in all material respects in conformity with generally accepted accounting principles. The purpose of this Staff Accounting Bulletin (''SAB'') is to provide guidance to financial management and independent auditors with respect to the evaluation of the materiality of misstatements that are identified in the audit process or preparation of the financial statements (*i.e.*, (b) above). This SAB is not intended to provide definitive guidance for assessing ''materiality'' in other contexts, such as evaluations of auditor independence, as other factors may apply. There may be other rules that address financial presentation. *See, e.g.*, Rule 2a–4, 17 CFR 270.2a–4, under the Investment Company Act of 1940.

[2] As used in this SAB, ''misstatement'' or ''omission'' refers to a financial statement assertion that would not be in conformity with GAAP.

[3] FASB, Statement of Financial Accounting Concepts No. 2, *Qualitative Characteristics of Accounting Information* (''Concepts Statement No. 2''), ¶ 132 (1980). *See also* Concepts Statement No. 2, Glossary of Terms—Materiality.

[4] *TSC Industries v. Northway, Inc.*, 426 U.S. 438, 449 (1976). *See also Basic, Inc.* v. *Levinson*, 485 U.S. 224 (1988). As the Supreme Court has noted, determinations of materiality require ''delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts and the significance of those inferences to him. . . . .'' *TSC Industries*, 426 U.S. at 450.

[5] *See, e.g.*, Concepts Statement No. 2, ¶¶ 123–124; AU § 312.10 (''. . . materiality judgments are made in light of surrounding circumstances and necessarily involve both quantitative and qualitative considerations.''); AU § 312.34 (''Qualitative considerations also influence the auditor in reaching a conclusion as to whether misstatements are material.''). As used in the accounting literature and in this SAB, ''qualitative'' materiality refers to the surrounding circumstances that inform an investor's evaluation of financial statement entries. Whether events may be material to investors for non-financial reasons is a matter not addressed by this SAB.

[6] *See, e.g.*, Rule 1–02(o) of Regulation S–X, 17 CFR 210.1–02(o), Rule 405 of Regulation C, 17 CFR 230.405, and Rule 12b–2, 17 CFR 240.12b–2; AU § § 312.10—.11, 317.13, 411.04 n. 1, and 508.36; *In re Kidder Peabody Securities Litigation*, 10 F. Supp. 2d 398 (S.D.N.Y. 1998); *Parnes v. Gateway 2000, Inc.*, 122 F.3d 539 (8th Cir. 1997); *In re Westinghouse Securities Litigation*, 90 F.3d 696 (3d Cir. 1996); *In the Matter of W.R. Grace & Co.*, Accounting and Auditing Enforcement Release No. (''AAER'') 1140 (June 30, 1999); *In the Matter of Eugene Gaughan*, AAER 1141 (June 30, 1999); *In the Matter of Thomas Scanlon*, AAER 1142 (June 30, 1999); and *In re Sensormatic Electronics Corporation*, Sec. Act Rel. No. 7518 (March 25, 1998).

[7] Concepts Statement No. 2, ¶ 131 (1980).

respect to a variety of disclosures.[8] And it took account of contradictory studies, one showing a lack of uniformity among auditors on materiality judgments, and another suggesting widespread use of a ''rule of thumb'' of five to ten percent of net income.[9] The FASB also considered whether an evaluation of materiality could be based solely on anticipating the market's reaction to accounting information.[10]

The FASB rejected a formulaic approach to discharging ''the onerous duty of making materiality decisions'' [11] in favor of an approach that takes into account all the relevant considerations. In so doing, it made clear that—

> [M]agnitude by itself, without regard to the nature of the item and the circumstances in which the judgment has to be made, will not generally be a sufficient basis for a materiality judgment.[12]

Evaluation of materiality requires a registrant and its auditor to consider *all* the relevant circumstances, and the staff believes that there are numerous circumstances in which misstatements below 5% could well be material. Qualitative factors may cause misstatements of quantitatively small amounts to be material; as stated in the auditing literature:

> As a result of the interaction of quantitative and qualitative considerations in materiality judgments, misstatements of relatively small amounts that come to the auditor's attention could have a material effect on the financial statements.[13]

Among the considerations that may well render material a quantitatively small misstatement of a financial statement item are—

- Whether the misstatement arises from an item capable of precise measurement or whether it arises from an estimate and, if so, the degree of imprecision inherent in the estimate [14]
- Whether the misstatement masks a change in earnings or other trends.
- Whether the misstatement hides a failure to meet analysts' consensus expectations for the enterprise.
- Whether the misstatement changes a loss into income or vice versa.
- Whether the misstatement concerns a segment or other portion of the registrant's business that has been identified as playing a significant role in the registrant's operations or profitability.
- Whether the misstatement affects the registrant's compliance with regulatory requirements.
- Whether the misstatement affects the registrant's compliance with loan covenants or other contractual requirements.
- Whether the misstatement has the effect of increasing management's compensation—for example, by satisfying requirements for the award of bonuses or other forms of incentive compensation.
- Whether the misstatement involves concealment of an unlawful transaction.

This is not an exhaustive list of the circumstances that may affect the materiality of a quantitatively small misstatement.[15] Among other factors, the demonstrated volatility of the price of a registrant's securities in response to certain types of disclosures may provide guidance as to whether investors regard quantitatively small misstatements as material. Consideration of potential market reaction to disclosure of a misstatement is by itself ''too blunt an instrument to be depended on'' in considering whether a fact is material.[16] When, however, management or the independent auditor expects (based, for example, on a pattern of market performance) that a known misstatement may result in a significant positive or negative market reaction, that expected reaction should be taken into account when considering whether a misstatement is material.[17]

For the reasons noted above, the staff believes that a registrant and the auditors of its financial statements should not assume that even small intentional misstatements in financial statements, for example those pursuant to actions to ''manage'' earnings, are immaterial.[18] While the intent of management does not render a misstatement material, it may provide significant evidence of materiality. The evidence may be particularly compelling where management has intentionally misstated items in the financial statements to ''manage'' reported earnings. In that instance, it presumably has done so believing that the resulting amounts and trends would be significant to users of the registrant's financial statements.[19] The staff believes that investors generally would regard as significant a management practice to over- or under-state earnings up to an amount just short of a percentage threshold in order to ''manage'' earnings. Investors presumably also would regard as significant an accounting practice that, in essence, rendered all earnings figures subject to a management-directed margin of misstatement.

The materiality of a misstatement may turn on where it appears in the financial statements. For example, a misstatement may involve a segment of the registrant's operations. In that instance, in assessing materiality of a misstatement to the financial statements taken as a whole, registrants and their auditors should consider not only the size of the misstatement but also the significance of the segment information to the financial statements taken as a whole.[20] ''A misstatement of the revenue and operating profit of a relatively small segment that is represented by management to be important to the future profitability of the entity'' [21] is more likely to be material to investors than a misstatement in a segment that management has not identified as especially important. In assessing the materiality of misstatements in segment information—as with materiality generally—

> situations may arise in practice where the auditor will conclude that a matter relating to segment information is qualitatively material even though, in his or her judgment, it is quantitatively immaterial to the financial statements taken as a whole.[22]

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[8] Concepts Statement No. 2, ¶¶ 131 and 166.

[9] Concepts Statement No. 2, ¶ 167.

[10] Concepts Statement No. 2, ¶¶ 168–69.

[11] Concepts Statement No. 2, ¶ 170.

[12] Concepts Statement No. 2, ¶¶ 125.

[13] AU § 312.11.

[14] As stated in Concepts Statement No. 2, ¶¶ 130:

> Another factor in materiality judgments is the degree of precision that is attainable in estimating the judgment item. The amount of deviation that is considered immaterial may increase as the attainable degree of precision decreases. For example, accounts payable usually can be estimated more accurately than can contingent liabilities arising from litigation or threats of it, and a deviation considered to be material in the first case may be quite trivial in the second.

This SAB is not intended to change current law or guidance in the accounting literature regarding accounting estimates. *See, e.g.*, Accounting Principles Board Opinion No. 20, *Accounting Changes* ¶¶ 10, 11, 31–33 (July 1971).

[15] The staff understands that the Big Five Audit Materiality Task Force (''Task Force'') was convened in March of 1998 and has made recommendations to the Auditing Standards Board including suggestions regarding communications with audit committees about unadjusted misstatements. *See generally* Big Five Audit Materiality Task Force, ''Materiality in a Financial Statement Audit—Considering Qualitative Factors When Evaluating Audit Findings'' (August 1998). The Task Force memorandum is available at www.aicpa.org.

[16] *See* Concepts Statement No. 2, ¶ 169.

[17] If management does not expect a significant market reaction, a misstatement still may be material and should be evaluated under the criteria discussed in this SAB.

[18] Intentional management of earnings and intentional misstatements, as used in this SAB, do not include insignificant errors and omissions that may occur in systems and recurring processes in the normal course of business. *See* notes 38 and 50 *infra*.

[19] Assessments of materiality should occur not only at year-end, but also during the preparation of each quarterly or interim financial statement. *See, e.g., In the Matter of Venator Group, Inc.*, AAER 1049 (June 29, 1998).

[20] *See, e.g., In the Matter of W.R. Grace & Co.*, AAER 1140 (June 30, 1999).

[21] AUI § 326.33.

[22] *Id.*

Aggregating and Netting Misstatements

In determining whether multiple misstatements cause the financial statements to be materially misstated, registrants and the auditors of their financial statements should consider each misstatement separately and the aggregate effect of all misstatements.[23] A registrant and its auditor should evaluate misstatements in light of quantitative and qualitative factors and ''consider whether, in relation to individual line item amounts, subtotals, or totals in the financial statements, they materially misstate the financial statements taken as a whole.'' [24] This requires consideration of—

> the significance of an item to a particular entity (for example, inventories to a manufacturing company), the pervasiveness of the misstatement (such as whether it affects the presentation of numerous financial statement items), and the effect of the misstatement on the financial statements taken as a whole. . . .[25]

Registrants and their auditors first should consider whether each misstatement is material, irrespective of its effect when combined with other misstatements. The literature notes that the analysis should consider whether the misstatement of ''individual amounts'' causes a material misstatement of the financial statements taken as a whole. As with materiality generally, this analysis requires consideration of both quantitative and qualitative factors.

If the misstatement of an individual amount causes the financial statements as a whole to be materially misstated, that effect cannot be eliminated by other misstatements whose effect may be to diminish the impact of the misstatement on other financial statement items. To take an obvious example, if a registrant's revenues are a material financial statement item and if they are materially overstated, the financial statements taken as a whole will be materially misleading even if the effect on earnings is completely offset by an equivalent overstatement of expenses.

Even though a misstatement of an individual amount may not cause the financial statements taken as a whole to be materially misstated, it may nonetheless, when aggregated with other misstatements, render the financial statements taken as a whole to be materially misleading. Registrants and the auditors of their financial statements accordingly should consider the effect of the misstatement on subtotals or totals. The auditor should aggregate all misstatements that affect each subtotal or total and consider whether the misstatements in the aggregate affect the subtotal or total in a way that causes the registrant's financial statements taken as a whole to be materially misleading.[26]

The staff believes that, in considering the aggregate effect of multiple misstatements on a subtotal or total, registrants and the auditors of their financial statements should exercise particular care when considering whether to offset (or the appropriateness of offsetting) a misstatement of an estimated amount with a misstatement of an item capable of precise measurement. As noted above, assessments of materiality should never be purely mechanical; given the imprecision inherent in estimates, there is by definition a corresponding imprecision in the aggregation of misstatements involving estimates with those that do not involve an estimate.

Registrants and auditors also should consider the effect of misstatements from prior periods on the current financial statements. For example, the auditing literature states,

> Matters underlying adjustments proposed by the auditor but not recorded by the entity could potentially cause future financial statements to be materially misstated, even though the auditor has concluded that the adjustments are not material to the current financial statements.[27]

This may be particularly the case where immaterial misstatements recur in several years and the cumulative effect becomes material in the current year.

2. Immaterial Misstatements That are Intentional

Facts: A registrant's management intentionally has made adjustments to various financial statement items in a manner inconsistent with GAAP. In each accounting period in which such actions were taken, none of the individual adjustments is by itself material, nor is the aggregate effect on the financial statements taken as a whole material for the period. The registrant's earnings ''management'' has been effected at the direction or acquiescence of management in the belief that any deviations from GAAP have been immaterial and that accordingly the accounting is permissible.

Question: In the staff's view, may a registrant make intentional immaterial misstatements in its financial statements?

Interpretive Response: No. In certain circumstances, intentional immaterial misstatements are unlawful.

Considerations of the Books and Records Provisions Under the Exchange Act

Even if misstatements are immaterial,[28] registrants must comply with Sections 13(b)(2)–(7) of the Securities Exchange Act of 1934 (the ''Exchange Act'').[29] Under these provisions, each registrant with securities registered pursuant to Section 12 of the Exchange Act,[30] or required to file reports pursuant to Section 15(d),[31] must make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets of the registrant and must maintain internal accounting controls that are sufficient to provide reasonable assurances that, among other things, transactions are recorded as necessary to permit the preparation of financial statements in conformity with GAAP.[32] In this context, determinations of what constitutes ''reasonable assurance'' and ''reasonable detail'' are based not on a ''materiality'' analysis but on the level

[23] The auditing literature notes that the ''concept of materiality recognizes that some matters, either individually or in the aggregate, are important for fair presentation of financial statements in conformity with generally accepted accounting principles.'' AU § 312.03. *See also* AU § 312.04.

[24] AU § 312.34. Quantitative materiality assessments often are made by comparing adjustments to revenues, gross profit, pretax and net income, total assets, stockholders' equity, or individual line items in the financial statements. The particular items in the financial statements to be considered as a basis for the materiality determination depend on the proposed adjustment to be made and other factors, such as those identified in this SAB. For example, an adjustment to inventory that is immaterial to pretax income or net income may be material to the financial statements because it may affect a working capital ratio or cause the registrant to be in default of loan covenants.

[25] AU § 508.36.

[26] AU § 312.34.

[27] AU § 380.09.

[28] FASB Statements of Financial Accounting Standards (''Standards'' or ''Statements'') generally provide that ''[t]he provisions of this Statement need not be applied to immaterial items.'' This SAB is consistent with that provision of the Statements. In theory, this language is subject to the interpretation that the registrant is free intentionally to set forth immaterial items in financial statements in a manner that plainly would be contrary to GAAP if the misstatement were material. The staff believes that the FASB did not intend this result.

[29] 15 U.S.C. § § 78m(b)(2)–(7).

[30] 15 U.S.C. § 78l.

[31] 15 U.S.C. § 78o(d).

[32] Criminal liability may be imposed if a person knowingly circumvents or knowingly fails to implement a system of internal accounting controls or knowingly falsifies books, records or accounts. 15 U.S.C. 78m(4) and (5). See also Rule 13b2–1 under the Exchange Act, 17 CFR 240.13b2–1, which states, ''No person shall, directly or indirectly, falsify or cause to be falsified, any book, record or account subject to Section 13(b)(2)(A) of the Securities Exchange Act.''

of detail and degree of assurance that would satisfy prudent officials in the conduct of their own affairs.[33] Accordingly, failure to record accurately immaterial items, in some instances, may result in violations of the securities laws.

The staff recognizes that there is limited authoritative guidance[34] regarding the ''reasonableness'' standard in Section 13(b)(2) of the Exchange Act. A principal statement of the Commission's policy in this area is set forth in an address given in 1981 by then Chairman Harold M. Williams.[35] In his address, Chairman Williams noted that, like materiality, ''reasonableness'' is not an ''absolute standard of exactitude for corporate records.''[36] Unlike materiality, however, ''reasonableness'' is not solely a measure of the significance of a financial statement item to investors. ''Reasonableness,'' in this context, reflects a judgment as to whether an issuer's failure to correct a known misstatement implicates the purposes underlying the accounting provisions of Sections 13(b)(2)–(7) of the Exchange Act.[37]

In assessing whether a misstatement results in a violation of a registrant's obligation to keep books and records that are accurate ''in reasonable detail,'' registrants and their auditors should consider, in addition to the factors discussed above concerning an evaluation of a misstatement's potential materiality, the factors set forth below.

- *The significance of the misstatement.* Though the staff does not believe that registrants need to make finely calibrated determinations of significance with respect to immaterial items, plainly it is ''reasonable'' to treat misstatements whose effects are clearly inconsequential differently than more significant ones.
- *How the misstatement arose.* It is unlikely that it is ever ''reasonable'' for registrants to record misstatements or not to correct known misstatements—even immaterial ones—as part of an ongoing effort directed by or known to senior management for the purposes of ''managing'' earnings. On the other hand, insignificant misstatements that arise from the operation of systems or recurring processes in the normal course of business generally will not cause a registrant's books to be inaccurate ''in reasonable detail.''[38]
- *The cost of correcting the misstatement.* The books and records provisions of the Exchange Act do not require registrants to make major expenditures to correct small misstatements.[39] Conversely, where there is little cost or delay involved in correcting a misstatement, failing to do so is unlikely to be ''reasonable.''
- *The clarity of authoritative accounting guidance with respect to the misstatement.* Where reasonable minds may differ about the appropriate accounting treatment of a financial statement item, a failure to correct it may not render the registrant's financial statements inaccurate ''in reasonable detail.'' Where, however, there is little ground for reasonable disagreement, the case for leaving a misstatement uncorrected is correspondingly weaker.

There may be other indicators of ''reasonableness'' that registrants and their auditors may ordinarily consider. Because the judgment is not mechanical, the staff will be inclined to continue to defer to judgments that ''allow a business, acting in good faith, to comply with the Act's accounting provisions in an innovative and cost-effective way.''[40]

The Auditor's Response to Intentional Misstatements

Section 10A(b) of the Exchange Act requires auditors to take certain actions upon discovery of an ''illegal act.''[41] The statute specifies that these obligations are triggered ''whether or not [the illegal acts are] perceived to have a material effect on the financial statements of the issuer. . . .'' Among other things, Section 10A(b)(1) requires the auditor to inform the appropriate level of management of an illegal act (unless clearly inconsequential) and assure that the registrant's audit committee is ''adequately informed'' with respect to the illegal act.

As noted, an intentional misstatement of immaterial items in a registrant's financial statements may violate Section 13(b)(2) of the Exchange Act and thus be an illegal act. When such a violation occurs, an auditor must take steps to see that the registrant's audit committee is ''adequately informed'' about the illegal act. Because Section 10A(b)(1) is triggered regardless of whether an illegal act has a material effect on the registrant's financial statements, where the illegal act consists of a misstatement in the registrant's financial statements, the auditor will be required to report that illegal act to the audit committee irrespective of any ''netting'' of the misstatements with other financial statement items.

The requirements of Section 10A echo the auditing literature. See, for example, Statement on Auditing Standards No. (''SAS'') 54, ''Illegal Acts by Clients,'' and SAS 82, ''Consideration of Fraud in a Financial Statement Audit.'' Pursuant to paragraph 38 of SAS 82, if the auditor determines there is evidence that fraud may exist, the auditor must discuss the matter with the appropriate level of management. The auditor must report directly to the audit committee fraud involving senior management and fraud that causes a material misstatement of the financial statements. Paragraph 4 of SAS 82 states that ''misstatements arising from fraudulent financial reporting are intentional misstatements or omissions of amounts or disclosures

[33] 15 U.S.C. § 78m(b)(7). The books and records provisions of section 13(b) of the Exchange Act originally were passed as part of the Foreign Corrupt Practices Act (''FCPA''). In the conference committee report regarding the 1988 amendments to the FCPA, the committee stated, ''The conference committee adopted the prudent man qualification in order to clarify that the current standard does not connote an unrealistic degree of exactitude or precision. The concept of reasonableness of necessity contemplates the weighing of a number of relevant factors, including the costs of compliance.'' Cong. Rec. H2116 (daily ed. April 20, 1988).

[34] So far as the staff is aware, there is only one judicial decision that discusses Section 13(b)(2) of the Exchange Act in any detail, *SEC* v. *World-Wide Coin Investments, Ltd.*, 567 F. Supp. 724 (N.D. Ga. 1983), and the courts generally have found that no private right of action exists under the accounting and books and records provisions of the Exchange Act. *See e.g., Lamb* v. *Phillip Morris Inc.*, 915 F.2d 1024 (6th Cir. 1990) and *JS Service Center Corporation* v. *General Electric Technical Services Company*, 937 F. Supp. 216 (S.D.N.Y. 1996).

[35] The Commission adopted the address as a formal statement of policy in Securities Exchange Act Release No. 17500 (January 29, 1981), 46 FR 11544 (February 9, 1981), 21 SEC Docket 1466 (February 10, 1981).

[36] *Id.* at 46 FR 11546.

[37] *Id.*

[38] For example, the conference report regarding the 1988 amendments to the FCPA stated, ''The Conferees intend to codify current Securities and Exchange Commission (SEC) enforcement policy that penalties not be imposed for insignificant or technical infractions or inadvertent conduct. The amendment adopted by the Conferees [Section 13(b)(4)] accomplishes this by providing that criminal penalties shall not be imposed for failing to comply with the FCPA's books and records or accounting provisions. This provision [Section 13(b)(5)] is meant to ensure that criminal penalties would be imposed where acts of commission or omission in keeping books or records or administering accounting controls have the purpose of falsifying books, records or accounts, or of circumventing the accounting controls set forth in the Act. This would include the deliberate falsification of books and records and other conduct calculated to evade the internal accounting controls requirement.'' Cong. Rec. H2115 (daily ed. April 20, 1988).

[39] As Chairman Williams noted with respect to the internal control provisions of the FCPA, ''[t]housands of dollars ordinarily should not be spent conserving hundreds.'' 46 FR 11546.

[40] *Id.*, at 11547.

[41] Section 10A(f) defines, for purposes of Section 10A, an *illegal act* as ''an act or omission that violates any law, or any rule or regulation having the force of law.'' This is broader than the definition of an ''illegal act'' in AU § 317.02, which states, ''Illegal acts'' by clients do not include personal misconduct by the entity's personnel unrelated to their business activities.''

in financial statements to deceive financial statement users.'' [42] SAS 82 further states that fraudulent financial reporting may involve falsification or alteration of accounting records; misrepresenting or omitting events, transactions or other information in the financial statements; and the intentional misapplication of accounting principles relating to amounts, classifications, the manner of presentation, or disclosures in the financial statements.[43] The clear implication of SAS 82 is that immaterial misstatements may be fraudulent financial reporting.[44]

Auditors that learn of intentional misstatements may also be required to (1) re-evaluate the degree of audit risk involved in the audit engagement, (2) determine whether to revise the nature, timing, and extent of audit procedures accordingly, and (3) consider whether to resign.[45]

Intentional misstatements also may signal the existence of reportable conditions or material weaknesses in the registrant's system of internal accounting control designed to detect and deter improper accounting and financial reporting.[46] As stated by the National Commission on Fraudulent Financial Reporting, also known as the Treadway Commission, in its 1987 report,

> The tone set by top management—the corporate environment or culture within which financial reporting occurs—is the most important factor contributing to the integrity of the financial reporting process. Notwithstanding an impressive set of written rules and procedures, if the tone set by management is lax, fraudulent financial reporting is more likely to occur.[47]

An auditor is required to report to a registrant's audit committee any reportable conditions or material weaknesses in a registrant's system of internal accounting control that the auditor discovers in the course of the examination of the registrant's financial statements.[48]

GAAP Precedence Over Industry Practice

Some have argued to the staff that registrants should be permitted to follow an industry accounting practice even though that practice is inconsistent with authoritative accounting literature. This situation might occur if a practice is developed when there are few transactions and the accounting results are clearly inconsequential, and that practice never changes despite a subsequent growth in the number or materiality of such transactions. The staff disagrees with this argument. Authoritative literature takes precedence over industry practice that is contrary to GAAP.[49]

General Comments

This SAB is not intended to change current law or guidance in the accounting or auditing literature.[50] This SAB and the authoritative accounting literature cannot specifically address all of the novel and complex business transactions and events that may occur. Accordingly, registrants may account for, and make disclosures about, these transactions and events based on analogies to similar situations or other factors. The staff may not, however, always be persuaded that a registrant's determination is the most appropriate under the circumstances. When disagreements occur after a transaction or an event has been reported, the consequences may be severe for registrants, auditors, and, most importantly, the users of financial statements who have a right to expect consistent accounting and reporting for, and disclosure of, similar transactions and events. The staff, therefore, encourages registrants and auditors to discuss on a timely basis with the staff proposed accounting treatments for, or disclosures about, transactions or events that are not specifically covered by the existing accounting literature.

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[42] AU § 316.04. See also AU § 316.03. An unintentional illegal act triggers the same procedures and considerations by the auditor as a fraudulent misstatement if the illegal act has a direct and material effect on the financial statements. See AU § § 110 n. 1, 316 n. 1, 317.05 and 317.07. Although distinguishing between intentional and unintentional misstatements is often difficult, the auditor must plan and perform the audit to obtain reasonable assurance that the financial statements are free of material misstatements in either case. See AU § 316 note 3.

[43] AU § 316.04. Although the auditor is not required to plan or perform the audit to detect misstatements that are immaterial to the financial statements, SAS 82 requires the auditor to evaluate several fraud ''risk factors'' that may bring such misstatements to his or her attention. For example, an analysis of fraud risk factors under SAS 82 must include, among other things, consideration of management's interest in maintaining or increasing the registrant's stock price or earnings trend through the use of unusually aggressive accounting practices, whether management has a practice of committing to analysts or others that it will achieve unduly aggressive or clearly unrealistic forecasts, and the existence of assets, liabilities, revenues, or expenses based on significant estimates that involve unusually subjective judgments or uncertainties. See AU § § 316.17*a* and .17*c*.

[44] AU §§ 316.34 and 316.35, in requiring the auditor to consider whether fraudulent misstatements are material, and in requiring differing responses depending on whether the misstatement is material, make clear that fraud can involve immaterial misstatements. Indeed, a misstatement can be ''inconsequential'' and still involve fraud.

Under SAS 82, assessing whether misstatements due to fraud are material to the financial statements is a ''cumulative process'' that should occur both during and at the completion of the audit. SAS 82 further states that this accumulation is primarily a ''qualitative matter'' based on the auditor's judgment. AU § 316.33. The staff believes that in making these assessments, management and auditors should refer to the discussion in Part 1 of this SAB.

[45] AU §§ 316.34 and 316.36. Auditors should document their determinations in accordance with AU § § 316.37, 319.57, 339, and other appropriate sections.

[46] *See, e.g.,* AU § 316.39.

[47] Report of the National Commission on Fraudulent Financial Reporting at 32 (October 1987). *See also* Report and Recommendations of the Blue Ribbon Committee on Improving the Effectiveness of Corporate Audit Committees (February 8, 1999).

[48] AU § 325.02. *See also* AU § 380.09, which, in discussing matters to be communicated by the auditor to the audit committee, states, ''The auditor should inform the audit committee about adjustments arising from the audit that could, in his judgment, either individually or in the aggregate, have a significant effect on the entity's financial reporting process. For purposes of this section, an audit adjustment, whether or not recorded by the entity, is a proposed correction of the financial statements. . . .''

[49] *See* AU § 411.05.

[50] The FASB Discussion Memorandum, *Criteria for Determining Materiality*, states that the financial accounting and reporting process considers that ''a great deal of the time might be spent during the accounting process considering insignificant matters . . . . If presentations of financial information are to be prepared economically on a timely basis and presented in a concise intelligible form, the concept of materiality is crucial.''

This SAB is not intended to require that misstatements arising from insignificant errors and omissions (individually and in the aggregate) arising from the normal recurring accounting close processes, such as a clerical error or an adjustment for a missed accounts payable invoice, always be corrected, even if the error is identified in the audit process and known to management. Management and the auditor would need to consider the various factors described elsewhere in this SAB in assessing whether such misstatements are material, need to be corrected to comply with the FCPA, or trigger procedures under Section 10A of the Exchange Act. Because this SAB does not change current law or guidance in the accounting or auditing literature, adherence to the principles described in this SAB should not raise the costs associated with recordkeeping or with audits of financial statements.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 91N–0281]

RIN 0910–AZ17

General and Plastic Surgery Devices; Effective Date of Requirement for Premarket Approval of the Silicone Inflatable Breast Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the silicone inflatable breast prosthesis, a generic type of medical device intended to augment or reconstruct the female breast. This device is made of a silicone shell that is inflated with sterile isotonic saline. Commercial distribution of this device must cease unless a manufacturer or importer has filed with FDA a PMA or PDP for its version of the silicone inflatable breast prosthesis within 90 days of the effective date of this regulation. This regulation reflects FDA's exercise of its discretion to require PMA's or PDP's for preamendments devices and is consistent with FDA's stated priorities and Congress' requirement that class III devices are to be regulated by FDA's premarket review. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997.

EFFECTIVE DATE: August 18, 1999.

FOR FURTHER INFORMATION CONTACT: Stephen P. Rhodes, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of June 24, 1988 (53 FR 23856), FDA published a final rule classifying into class III (premarket approval) the silicone inflatable breast prosthesis, a medical device. Section 878.3530 (21 CFR 878.3530) of FDA's regulations setting forth the classification of the silicone inflatable breast prosthesis applies to: (1) Any silicone inflatable breast prosthesis that was in commercial distribution before May 28, 1976, and (2) any device that FDA has found to be substantially equivalent to a silicone inflatable breast prosthesis in commercial distribution before May 28, 1976.

In an advanced notice of proposed rulemaking published in the **Federal Register** of January 6, 1989 (54 FR 550), the agency identified the silicone inflatable breast prosthesis as one of the high-priority devices that would be subject to PMA or PDP requirements. FDA issued a notice in the **Federal Register** of September 26, 1991 (56 FR 49098), requiring manufacturers to disseminate information on risks associated with the silicone gel-filled breast prosthesis and the silicone inflatable breast prosthesis. FDA stated that either type of breast prosthesis would be misbranded under the act if its labeling did not provide adequate information for patients.

In the **Federal Register** of January 8, 1993 (58 FR 3436), FDA published a proposed rule, under section 515(b) of the act (21 U.S.C. 360e(b)), to require the filing of PMA's or PDP's for the classified silicone inflatable breast prosthesis and all substantially equivalent devices. In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble, the agency's proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements of the act, and (2) the benefits to the public from use of the device.

The preamble also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's proposed findings. Under section 515(b)(2)(B) of the act, it also provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the silicone inflatable breast prosthesis was required to be submitted by January 25, 1993. The comment period initially closed on March 6, 1993. In the **Federal Register** of March 10, 1993 (58 FR 13230), FDA extended the comment period for 30 days to April 8, 1993, to ensure that there was adequate time for preparation and submission of comments on the proposed rule.

The agency received 134 comments in response to the January 8, 1993, proposed rule. These comments were from individuals, manufacturers, professional societies, and consumer and health groups. Most of the comments supported the proposed rule.

In the **Federal Register** of June 28, 1995 (60 FR 33608), FDA issued a notice announcing the availability of an updated patient risk information booklet, entitled ''Information for Women Considering Saline-filled Breast Implants.'' The information booklet provided prospective patients with information about possible risks involved with silicone inflatable breast prostheses. FDA gave the updated information booklet to the manufacturers of saline-filled breast implants (silicone inflatable breast prostheses) to include with their labeling. FDA intended that physicians who perform breast implant surgery give this information to their patients as they considered implantation of a silicone inflatable breast prosthesis.

FDA is aware that new information on the device has become available since the proposed rule was published in January 1993. On June 2, 1999, the Institute of Medicine (IOM) released a comprehensive review of the published literature and ongoing studies on both saline-filled and silicone gel-filled breast implants entitled ''Safety of Silicone Breast Implants.'' Both of these types of implants have a silicone elastomer shell. The IOM made a clear distinction between local complications and systemic health concerns. The IOM determined that there was insufficient evidence to establish that breast implants cause systemic health effects such as autoimmune disease. The IOM concluded that there is ''no definitive evidence linking breast implants to cancer, immunological diseases, neurological problems, or other systemic diseases. On the basis of our committee's review of the data, we concluded that women with breast implants are no more likely than other women to develop these systemic illnesses.'' However, the IOM also concluded that local complications are ''the primary safety issue with silicone breast implants.'' These local complications include rupture, pain, capsular contracture, disfigurement, and serious infection, which may lead to medical interventions and repeat surgeries. The agency believes that local complications should be addressed in a PMA or PDP submission. Therefore, while it is possible that the level of risk presented by the device may differ somewhat from that described in the proposal, FDA nevertheless believes that the risks to health identified in the proposed rule still exist for the device and consequently, should be addressed in PMA's or PDP's for the device.

This regulation is final upon publication and requires PMA's or notices of completion of a PDP for all silicone inflatable breast prostheses classified under § 878.3530 and all devices that are substantially equivalent to them. PMA's or notices of completion of a PDP for these devices must be filed with FDA within 90 days of the effective date of this regulation. (See section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)).) This regulation does not include the silicone gel-filled breast prosthesis (21 CFR 878.3540).

II. Summary and Analysis of Comments and FDA's Response

A. General Comments

1. FDA received comments from 116 women consumers and six health professionals supporting the proposed call for PMA's or PDP's. Sixty-four of the women consumers were reconstruction or augmentation patients who were dissatisfied with their implants. These women believed that their breast implants have caused them adverse health effects. Fourteen of these breast implant recipients provided medical histories and patient records to support their belief that their illnesses are associated with their breast implants. Seven other comments also expressed the belief that breast prostheses cause adverse health effects. The other 43 women did not indicate whether or not they had been implanted with breast implants. Nineteen of these 43 comments recommended that silicone inflatable breast prostheses be recalled and banned until long-term safety and effectiveness studies are completed. Some comments recommended that silicone gel-filled breast prostheses be recalled and banned. Thirty-one women expressed strong opinions that the risks associated with all breast implants are unacceptable.

FDA does not believe that the available evidence supports a conclusion that either banning or recalling the device would be appropriate. Rather, FDA believes that requiring the submission of PMA's or PDP's for the silicone inflatable breast prosthesis will provide FDA an opportunity to assess more fully the risks and benefits of these devices in order to determine whether there is reasonable assurance of their safety and effectiveness, or absent such an assurance what regulatory course should be taken.

The comments addressing the silicone gel-filled breast implant are not within the scope of this rule. In the **Federal Register** of April 10, 1991 (56 FR 14620), FDA issued a final rule requiring the submission of PMA's or PDP's for the silicone gel-filled breast prosthesis.

2. One comment stated that PMA's or PDP's are not necessary for this device because adequate studies on silicone toxicity already exist establishing the safety and effectiveness of the silicone inflatable breast prosthesis. This comment stated that the extensive published research has not found any causal relationship between silicone-containing breast prostheses and the adverse events observed in some women with these devices. Other comments stated that existing information on the silicone gel-filled breast prosthesis and on other types of silicone-containing prostheses in use (the chin prosthesis (21 CFR 878.3550); the ear prosthesis (21 CFR 878.3590), and the finger joint prosthesis (21 CFR 888.3230)) provide adequate information to support the safety and effectiveness of the silicone inflatable breast prosthesis.

FDA is aware of the existence of information on silicone and silicone-containing prostheses and expects that applicants may include such information in their submissions to establish the safety and effectiveness of the silicone inflatable breast prosthesis. FDA will consider all information contained in PMA's or PDP's in determining whether there is reasonable assurance of the safety and effectiveness of these devices.

3. Four comments suggested that additional guidance on the data requirements for PMA's be made available before publishing the final rule. One of these comments also requested an open dialogue between FDA, the industry, and the scientific and medical communities to develop a consensus on the preclinical and clinical data necessary to establish the safety and effectiveness of the device, and reissuance of the proposed rule with a longer timeframe.

The 1993 proposed rule provided guidance on the appropriate data to be included in the PMA for the silicone inflatable breast prosthesis. Although section 515(b) of the act does not require the agency to provide specific guidance on the contents of specific PMA's, FDA has issued a ''Draft Guidance for the Preparation of PMA Application for Silicone Inflatable (Saline) Breast Prostheses'' in November 1994 and a revised draft guidance in January 1995 (the 1995 guidance document). The 1995 guidance document is available from the internet at ''www.fda.gov/cdrh/ode/odegr532.html''. In order to receive the ''Draft Guidance for Silicone Inflatable (Saline) Breast Prostheses'' via your fax machine, call CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number (223) followed by the pound sign (#). Follow the remaining voice prompts to complete you request.

In June 1996, FDA sent known manufacturers of the silicone inflatable breast prosthesis a letter describing the recommended data for a PMA. The period of time between the classification of the device in 1988 and the date by which PMA's must be filed is more than 10 years. Thus, FDA believes that sufficient time and guidance has been provided to allow sponsors to develop the data for a PMA submission. FDA agrees that dialogue with industry and with the scientific and medical community is important; FDA staff have been and continue to be accessible to discuss PMA and PDP content information with industry and the scientific and medical community.

4. Two comments suggested that postapproval studies could be used to support approval of the silicone inflatable breast prosthesis, and another comment suggested the use of FDA's postmarket surveillance authority.

FDA notes that, by definition, postapproval studies are studies performed after the approval of a PMA and that postmarket surveillance studies are studies used to acquire additional performance information about a device already determined to be reasonably safe and effective. In the 1993 proposed rule, FDA stated that postapproval studies would be required to fully assess the potential carcinogenicity and teratogenicity of any approved silicone inflatable breast prostheses. In the 1995 guidance document, FDA restated this need for postapproval studies and added that postapproval studies would also be needed to assess the potential for causing adverse immunological effects and/or connective tissue disorders.

5. One comment objected that Congress never intended ''old'' preamendments medical devices to undergo the same scrutiny as ''new'' postamendments medical devices.

FDA does not believe that Congress intended to differentiate between ''old'' preamendments devices and ''new'' postamendments devices with respect to the requirement that valid scientific evidence is needed to support PMA approval. Neither section 513(a)(3) (21 U.S.C. 360c(a)(3)) nor section 515(d) of the act makes any distinction between ''old'' and ''new'' devices with regard to any aspect of the requirement for PMA approval. Evidence that constitutes valid scientific evidence within the meaning of § 860.7(c)(2) (21 CFR 860.7(c)(2)) may be submitted in support of a PMA or PDP, but it will remain the agency's judgment whether the submitted evidence provides reasonable assurance of safety and effectiveness.

6. Six comments stated that tissue expanders should be not be included in the call for PMA's or PDP's. Five comments said that tissue expanders intended for short-term use are unclassified devices. One comment

suggested that the tissue expander intended for short-term use should be classified into class II and that the tissue expander intended for long-term use should be classified into class III.

Saline-filled silicone tissue expanders are used for general surgical procedures, as well as for breast implantation surgery. FDA agrees that tissue expanders intended for short-term use or for general surgical purposes are unclassified devices and are not covered in this final rule. FDA plans to initiate classification procedures for that device at a future date. However, saline inflatable tissue expanders that meet the definition of a silicone inflatable breast prosthesis are included in this final rule.

7. One comment said the risk section should be rewritten because it reflects an agency bias against the silicone inflatable breast prosthesis, in that it equates the risks associated with the silicone inflatable breast prosthesis with those of the silicone gel-filled breast prosthesis.

FDA disagrees. The preamble to the proposed rule clearly states that much of the literature cited in the risk section of the proposed rule referred specifically to the silicone inflatable breast prosthesis. The agency cited information about other silicone devices only where there was no documentation specific to the silicone inflatable breast prosthesis. Comparison of risk information between devices should not be confused with an equation of risk.

B. Fibrous Capsular Contraction

8. There were six comments on the risk of fibrous capsular contracture. These comments indicated that fibrous capsule formation occurs around any implanted device and that this is part of the healing process. They stated that, although this risk to health is a frequent outcome, it is not life-threatening, and should be considered a relatively minor risk to health.

FDA agrees that fibrous capsular contracture is usually not life-threatening and that normal fibrous capsule formation is part of the wound healing process after the implantation of any prosthesis. Fibrous capsular contracture, however, is associated with clinical changes ranging from a nearly imperceptible deformation of the implant to marked distortion and firmness, often accompanied by tenderness, pain, and discomfort. Significant fibrous capsular contracture, Baker grades 3 and 4, may require surgical removal of the device, making contracture a serious risk to health. As stated in the 1995 guidance document, FDA is requesting time-course data on the rate and frequency of fibrous capsular contracture.

C. Deflation

9. There were seven comments on the risk of deflation. Two comments said that deflation is not life-threatening, two characterized deflation as being of low or no risk, and three said it is infrequent.

FDA agrees that this risk to health is not life-threatening. However, deflation of the silicone inflatable breast prosthesis eliminates the benefit of the device. In addition, the recipient may then elect to have her implant surgically explanted and have a second breast prosthesis implanted. This additional surgery makes deflation a potentially serious adverse event. As noted in the 1995 guidance document, FDA requested information to address the incidence of deflation and rupture for this device.

D. Infection

10. Four comments stated that the incidence of infection associated with the implantation of silicone inflatable breast prostheses is not any higher than it is for other implantation surgeries. One comment said that FDA needs an accurate determination of the incidence of infection in women implanted with silicone inflatable breast prostheses.

FDA believes that it is important for studies submitted in a PMA or PDP to provide accurate information on the incidence of infection associated with the implantation of the silicone inflatable breast prosthesis.

E. Interference With Early Tumor Detection

11. Several comments stated that mammography may be more difficult to perform and that it may be less effective for the early detection of tumors in women with breast implants. Two other comments disagreed, stating that there are no data showing that the presence of breast implants has hindered or delayed the detection of breast tumors. The same comments stated that implantation of the device under the pectoralis muscles may reduce the interference with mammography, that interference can be overcome with special detection procedures, and that cancer detection does not rely solely on mammography.

FDA agrees that the presence of a silicone inflatable breast prosthesis may interfere with the standard mammography procedures used to screen patients for breast cancer. The device may produce a shadow on the radiograph that obscures visualization of a significant portion of the breast. In addition, the prosthesis compresses overlying breast tissue, reducing contrast and making mammographic assessment more difficult. Mammography of the augmented or reconstructed breast requires special techniques, which may result in increased exposure to radiation. Even under the best of circumstances, silicone inflatable breast prostheses are likely to limit the effectiveness of this examination for breast cancer detection. As stated in the 1995 guidance document, FDA is requesting information on the potential interference of the silicone inflatable breast prosthesis on the ability of mammography to detect tumors in breast tissue.

F. Human Carcinogenicity

12. Nine comments said that there is no established correlation between cancer and women with a silicone inflatable breast prosthesis. They stated that silicone causes solid state tumors in rodents, a phenomenon thought to be restricted to rodents and not applicable to humans. They also stated that epidemiological studies have not found that women with breast implants are at an increased risk for cancer.

FDA believes that the potential carcinogenicity for this device remains unknown. The agency continues to believe that carcinogenicity is a potential risk that must be assessed in a PMA or PDP.

G. Human Teratogenicity

13. There were five comments related to human teratogenicity. Three comments stated that there is no evidence that the silicone inflatable breast prosthesis is teratogenic. Two comments stated that teratogenicity is a remote risk, which could be addressed in postapproval studies. One comment stated that seven studies published between 1975 and 1993 (including the literature FDA cited in the proposed rule), in conjunction with the absence of reports of defects among children born to women who have undergone mammary augmentation/reconstruction with silicone implants, indicates that teratogenicity is not an identified or a potential risk to health.

FDA agrees that there are no published studies showing that silicone inflatable prostheses are associated with toxic reproductive effects or teratogenic effects. However, FDA believes that teratogenicity and/or reproductive effects of silicone elastomers remain potential risks that should be assessed in a PMA or PDP. This information was requested in the proposed rule and in the 1995 guidance document.

H. Adverse Immunological Effects and/or Connective Tissue Disorders

14. Five comments stated that no definitive link between silicone and autoimmune diseases has been established. These comments stated that the incidence of these diseases in women with breast implants is no higher than it is in women without breast implants. Two of these comments suggested that some women may be more genetically susceptible to the immunological effects than others. As stated previously, 71 consumer comments expressed the belief that breast implants cause unacceptable adverse health effects. One physician reported that his patients with breast prostheses had a higher than expected prevalence of positive antinuclear antibody (ANA) test results. Because there was no difference in the ANA test results between patients with gel-filled and saline-filled breast prostheses, this comment attributed the positive ANA results for both patient populations to the silicone shell of the prostheses.

FDA agrees that no definitive causal relationship has been established between immunological effects and/or connective tissue disorders and the silicone inflatable breast prosthesis. FDA is aware of the concerns expressed in the consumer comments. FDA also recognizes that a positive ANA test without clinical symptoms is a nonspecific finding. In the 1995 guidance document, FDA recommended that recipients of silicone inflatable breast prostheses be regularly monitored for the occurrence of such adverse events for a minimum of 10 years postimplantation. FDA continues to believe that adverse immunological effects and/or connective tissue disorders remain potential risks that must be assessed in a PMA or PDP, but FDA does not believe that 10 years of prospective data collection on a specific product will be necessary to do so.

I. Calcification

15. Several comments stated that calcification is not life-threatening and is of unknown clinical significance. Other comments suggest that calcification: (1) May occur in as many as 25 percent of breast implant patients; (2) is rare; (3) is closely associated with capsular contracture; (4) may complicate the interpretation of mammograms; and (5) may cause abrasions of the silicone shell of the device if the calcium salt crystals have sharp edges, making the implant more susceptible to rupture.

FDA believes that there is not much information on the incidence and effects of calcification in women implanted with silicone inflatable breast prostheses. FDA believes that calcification remains an uncharacterized potential risk to health. Consequently, as stated in the proposed rule, FDA believes that PMA's or PDP's for this device should include time-course information on the incidence of calcification.

J. Biological Effects of Silica

16. Several comments stated that fumed amorphous silica is so tightly bound in the silicone elastomer shell of the silicone inflatable breast prosthesis that the fumed amorphous silica is biologically inactive. For that reason, these comments believed that the presence of fumed amorphous silica is not a risk to health of the silicone inflatable breast prosthesis.

FDA does not believe there is sufficient information to eliminate fumed amorphous silica as a potential risk to health associated with the silicone inflatable breast prosthesis, particularly since the amount of fumed amorphous silica is varied in order to achieve the desired physical characteristics of the shell. Consequently, the agency believes that this potential risk to health should be addressed in a PMA or PDP.

K. Interference With Breast Feeding

17. Several comments stated that the presence of the silicone inflatable breast prosthesis could potentially interfere with the breast feeding of infants. The comments objected that claims that breast implants have no effect on the nursing of infants are unsubstantiated.

FDA agrees that interference with breast feeding of infants is a potential risk to health presented by this device because the implants may reduce the ability of breast feeding women to deliver an adequate quantity of milk. Although most augmentation patients are of childbearing age, there are no data on this potential risk. FDA believes that PMA's or PDP's for the silicone inflatable breast prosthesis should contain information on the effect of the device on the breast feeding of infants.

L. Benefits of the Device

18. One comment stated that a positive psychological benefit for the silicone inflatable breast prosthesis should be assumed. Other comments maintained that the published studies have already established that breast prostheses provide a positive psychological benefit.

The agency believes that the potential psychological benefits offered by the device are an important part of the device's efficacy. Consequently, FDA believes the psychological benefit of the silicone inflatable breast prosthesis should be demonstrated in clinical trials and reported in a PMA or PDP application.

19. Seven comments stated that the determination of psychological benefit is problematic for several reasons: (1) There are no validated standardized psychological tests for measuring psychological benefit; (2) existing tests for psychological well-being and self-esteem are confounded by multiple life variables, including the patient's general health, sexual functioning, and understanding of the potential complications when making the decision to have a silicone inflatable breast prosthesis implanted; and (3) there is a lack of suitable controls for both reconstruction and augmentation patients. One comment suggested that benefit be assessed with ''quality of life'' questionnaires, using patients as their own controls and assessing a wide range of variables. Another comment stated that it would be ''unduly burdensome and needlessly distressful'' to subject women requesting breast implants to psychological assessment testing.

Among the seven comments there was general agreement that patients should be followed for a long period of time after the surgery, perhaps even 10 to 15 years. This is complicated because, during this period, other issues related to self-esteem and a feeling of well-being may confound the determination of psychological benefit. Some comments stated that the assessment of psychological benefit should be different for reconstruction and augmentation patients.

FDA agrees that designing studies to assess the psychological benefit of implantation with a silicone inflatable breast prosthesis may be difficult. In the 1995 guidance document, FDA suggested that the effectiveness of the device can be measured by assessing: (1) The degree of maintenance (if applicable) or of enhancement of a woman's psychological well-being postimplantation, and (2) the anatomical effect provided by the device. FDA added that both assessments should be balanced against any illness or injury associated with the use of the device. FDA further stated that the level of benefit derived from the device may depend on whether the device is used for augmentation mammoplasty, correction of congenital or traumatic breast anomalies, or reconstruction mammoplasty after tumor removal, and recommended that benefit data be stratified by these categories of use. The agency will accept

a variety of types of scientific evidence in support of a PMA or PDP, as long as the data constitute valid scientific evidence within the meaning of § 860.7(c)(2).

M. Need for Risk Benefit Information

20. Three comments agreed that risk/benefit data should be collected, but questioned the need to include such data in a PMA.

FDA believes that it is appropriate for PMA's or PDP's to contain risk/benefit data to enable the agency to determine whether there is reasonable assurance of the safety and effectiveness of the silicone inflatable breast prosthesis.

N. PMA Contents

21. FDA received two extensive comments on the types of manufacturing information, preclinical testing, and clinical data that should be required in a PMA for a silicone inflatable breast prosthesis, as well as several general comments on the appropriate contents of a PMA.

FDA believes that the points raised in these comments are addressed in great detail in the 1995 draft guidance. The guidance addresses all types of data, including manufacturing, preclinical, and clinical, expected to be submitted. Additionally, manufacturers already have begun submitting manufacturing and preclinical data to the agency in preparation for the call for PMA's or PDP's.

III. Findings With Respect to Risks and Benefits

A. Degree of Risk

1. Fibrous Capsular Contracture

Contracture, the formation of a constricting fibrous layer around the silicone inflatable breast prosthesis, is a risk associated with both augmentation and reconstruction mammoplasty. Contracture may result in excessive breast firmness, discomfort, pain, disfigurement, displacement of the implant, and psychological trauma. Procedures, including corrective surgery or surgical removal of the device and adjacent tissue, may be required to relieve the symptoms associated with contracture. The effects of contracture can vary from a reduced satisfaction with the device to causing a woman to seek explantation of the device. Although severe cases are rare, less severe contracture is the most common adverse event associated with the silicone inflatable breast prosthesis.

2. Deflation

The deflation of a silicone inflatable breast prosthesis is the loss of saline volume from the device as a result of rupture, valve failure, or a defect in the device. Deflation is not life-threatening, but the loss of saline destroys the shape of the implant, and surgery may be required to remove and replace it. Because of the need for an additional surgery, deflation is a serious adverse event. Deflation incidence data, as a function of time after implantation, are not currently available.

3. Infection

Infection is a risk associated with any surgical implant procedure, including implantation of the silicone inflatable breast prosthesis. Compromised device sterility and surgical techniques may be major contributing factors to this risk. Skin and bacteremic flora may also have a role in infection in the periprosthetic area. Infection may increase fibrous capsular contracture and result in a need for removal of the device.

4. Interference With Early Tumor Detection

The presence of a silicone inflatable breast prosthesis may interfere with standard mammography procedures by producing a shadow that obscures visualization, or by reducing contrast by compressing overlying breast tissue. Mammography of the augmented breast requires special techniques and skills and may result in increased exposure to radiation.

5. Human Carcinogenicity

The potential for developing cancer as a result of the long-term implantation of silicone inflatable breast prostheses cannot be eliminated as a potential risk associated with the silicone inflatable breast prosthesis.

6. Human Teratogenicity

Although FDA is not aware of data indicating that the silicone inflatable breast prosthesis is associated with teratogenic and reproductive effects, the potential for teratogenicity and other reproductive adverse effects as a result of long-term implantation of the device cannot be eliminated as a possible risk to health. Reproductive effects are particularly important because many augmentation patients are of childbearing age.

7. Adverse Immunological Effects and/or Connective Tissue Disorders

The potential for developing immunological effects and/or connective tissue disorders as a result of long-term exposure to the silicone inflatable breast prosthesis remains uncertain. Since the publication of the proposed rule 5 years ago, new epidemiological data (Refs. 1 and 2) addressing the relationship between the device and autoimmune diseases or connective tissue diseases indicate that silicone breast prostheses have not caused a large increase in the incidence of connective tissue disease in women with breast implants. However, the possibility of a smaller increased risk of immunological effects, or of an atypical, as yet undefined, syndrome or disease, cannot be eliminated based on these data.

8. Calcification

Calcification of the fibrous capsule surrounding the silicone inflatable breast prosthesis involves the deposition of mineral salts in the capsule. Neither the incidence nor the risk to health of calcification are established.

9. Biological Effects of Silica

Amorphous fumed silica is bound to the silicone in the elastomeric shell of the silicone inflatable breast prosthesis. Silica presents a potential risk which should be addressed in a PMA or PDP.

B. Benefits of the Device

The silicone inflatable breast prosthesis is intended to reconstruct or augment the female breast. Reconstruction or augmentation surgery is elective in nature, although implantation of a silicone inflatable breast prosthesis is often an integral part of the reconstructive patient's total treatment.

Although a definitive psychological study to assess the benefits of the silicone inflatable breast prosthesis may be difficult to conduct, FDA believes data are needed to document whether the device is effective for its intended use.

IV. Final Rule

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the preamble to the proposed rule and is issuing this final rule to require premarket approval of the generic type of device, the silicone inflatable breast prosthesis, by revising § 878.3530(c).

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed on or before November 17, 1999, for any silicone inflatable breast prosthesis that was in commercial distribution before May 28, 1976, or that has been found by FDA to be substantially equivalent to such a device on or before November 17, 1999. An approved PMA or a declared completed PDP is required to be in effect for any such device on or before 180 days after FDA files the application.

Any other silicone inflatable breast prosthesis that was not in commercial distribution before May 28, 1976, or that has not been found by FDA to be substantially equivalent to such a device on or before November 17, 1999, is required to have an approved PMA or a declared completed PDP in effect before it may be marketed.

If a PMA or a notice of completion of a PDP for a silicone inflatable breast prosthesis is not filed on or before the 90th day past the effective date of this regulation, that device will be deemed adulterated under section 501(f)(1)(A) of the act , and commercial distribution of the device will be required to cease immediately. The device may, however, be distributed for investigational use, if the requirements of the investigational device exemption (IDE) regulations (part 812) (21 CFR part 812) are met.

Under § 812.2(d) of the IDE regulations, FDA hereby stipulates that, on the effective date of this rule, the exemptions from the IDE requirements in § 812.2(c)(1) and (c)(2) will no longer apply to clinical investigations of the silicone inflatable breast prosthesis. Further, FDA concludes that investigational silicone inflatable breast prostheses are significant risk devices as defined in § 812.3(m) and advises that, as of the effective date of this rule, the requirements of the IDE regulations regarding significant risk devices will apply to any clinical investigation of a silicone inflatable breast prosthesis. For any silicone inflatable breast prosthesis that is not the subject of a timely filed PMA or PDP, an IDE must be in effect under § 812.20 on or before 90 days after the effective date of this regulation or distribution of the device must cease. FDA advises all persons presently sponsoring a clinical investigation involving the silicone inflatable breast prosthesis to submit an IDE application to FDA no later than 60 days after the effective date of this final rule to avoid the interruption of ongoing investigations.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by subtitle D of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 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). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The Office of Management and Budget (OMB) has determined that this final rule is a significant regulatory action subject to review under the Executive Order.

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA expects that up to seven manufacturers will submit a PMA or PDP for the silicone inflatable breast prosthesis. FDA estimates that it costs up to $1 million to submit a PMA or PDP. As noted previously, the silicone inflatable breast prosthesis was classified into class III on June 24, 1988, and FDA published a proposed rule to require a PMA or PDP for this device on January 8, 1993. Thus, manufacturers have long been aware of the need to develop information in support of a PMA or a PDP. Moreover, since the publication of the proposed rule, FDA has been working closely with manufacturers to assist them in preparing for the submission of a PMA or a PDP. FDA, therefore, believes that this final rule will not be an undue burden on these manufacturers. The agency therefore certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3530). The burden hours required for § 878.3530(c) are reported and approved under OMB Control No. 0910–0231.

VIII. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. These references may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

1. Hennekens, C. H., I. Lee, N. Cook, P. R. Hebert, E. W. Karlson, F. LaMotte, J. E. Manson, and J. E. Buring, ''Self-reported Breast Implants and Connective-Tissue Diseases in Female Health Professionals,'' *Journal of the American Medical Association*, 275:616–621, 1996.

2. Silverman, B. G., S. L. Brown, R. A. Bright, R. G. Kaczmarek, J. B. Arrowsmith-Lowe, and D. A. Kessler, ''Reported Complications of Silicone Gel Breast Implants: An Epidemiologic Review,'' *Annals of Internal Medicine*, 124:744–756, 1996.

3. Institute of Medicine, ''Safety of Silicone Breast Implants,'' National Academy Press, Washington, DC, 1999.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 878.3530 is amended by revising paragraph (c) to read as follows:

§ 878.3530 Silicone inflatable breast prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 17, 1999, for any silicone inflatable breast prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before November 17, 1999, been found to be substantially equivalent to a silicone inflatable breast prosthesis that was in commercial distribution before May 28, 1976. Any other silicone inflatable breast prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: March 29, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–21508 Filed 8–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 2976]

RIN 1400–AA90

Visas: Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended—Border Crossing Cards

AGENCY: Department of State, Bureau of Consular Affairs.

ACTION: Final rule.

SUMMARY: This is a final rule adopting and/or amending Department of State regulations pertaining to the nonimmigrant border crossing identification card (BCC) and those pertaining to the requirements for entry of Mexican nationals into the United States. The rule is necessitated, in part, by a change in the law, which now specifies that regulations pertaining to the BCC contain a requirement for the inclusion of a machine-readable biometric identifier in such cards.

The rule provides authority for consular officers to issue to Mexican citizens who are residents of Mexico a combined B–1/B–2 visa and border crossing card (B–1/B–2 Visa/BCC) as a stand-alone card containing a machine-readable biometric identifier; specifies the conditions under which the new stand-alone card will be considered invalidated; waives the requirements for the presentation of a passport for all applicants for the card, provided the applicant presents other acceptable documentation of nationality and identity; includes a waiver of the visa and passport requirement for Mexican nationals entering the United States for the purpose of obtaining official Mexican documents from a Mexican consular office in the United States side of the border; and adopts changes to the regulations pertaining to the issuance and revocation of Canadian border crossing cards made necessary by the same change in the law.

EFFECTIVE DATE: August 19, 1999.

FOR FURTHER INFORMATION CONTACT: H. Edward Odom, Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20520–0106, (202) 663–1204, odomhe@state.gov.

SUPPLEMENTARY INFORMATION: The Department published an interim rule with request for comments [63 FR 16895] on April 7, 1998. The Department received one timely comment in response to the interim rule. This final rule adopts without changes the revisions made in the interim rule to sections 41.2(g) and 41.122(a)(4). The rule adopts, with minor word changes, the revisions to sections 41.32 and 41.33.

Analysis of Comment

The comment received expressed a concern that requiring the biometric reader in the card could cause significant time increases for processing the large volume of traffic that crosses the land borders between the United States and Canada and the United States and Mexico. The commentator specifically focused on the negative effect the BCC would have on time-sensitive commercial trade flows between the United States and its two largest trading partners.

The Department's regulations, however, deal with the content and issuance of the BCC, and not the processing of the cards at land borders between the United States, Canada and Mexico. Those procedures are left to the Immigration and Naturalization Service. Further, both the information on the face of the card and the biometric data contained in the card have been designed to ensure rapid processing of traffic on land-borders. The Department believes, therefore, that the design of the card has been tailored in a fashion that meets both the Congressional directive to include a biometric identifier in the BCC/NIV, in an effort to ameliorate the incidence of fraud associated with the card, and the commentator's concern of ensuring ease of commerce between the United States and its neighbors. Finally, the commentator suggested that the BCC/NIV biometric program be delayed pending a study of its potential effect on land border traffic. The Department, however, was constrained by IIRIRA § 104 to begin issuance of biometric inclusive cards as of April 1, 1998. The Department, therefore, does not deem it necessary to comply with the commenter's request.

Passport Requirement

When originally published, the interim rule contained an amendment to 22 CFR 41.2(g)(4) reflecting an agreement pursuant to INA 212(d)(4) between the Department of State and the INS to waive the passport requirement contained in INA 212(a)(7)(B)(i)(I) for certain applicants for the new B–1/B–2 Visa/BCC. This agreement also was reflected in the language of 22 CFR 41.32(a)(2)(iii) in the interim rule. Since that time, however, the Department and INS have agreed to a further change in policy regarding the documentation necessary for the BCC application process.

Recently, the Department gained information that Mexican authorities adjudicate the application for a Certificate of Mexican Nationality (CMN) as rigorously as a Mexican passport application. In addition, if a consular officer has a question regarding the validity of a CMN, the means to investigate the situation has been shown to be similar to that of investigating a questionable passport. The Department has determined, therefore, that the CMN, when used in conjunction with another piece of identification that includes a photo, will be sufficient for consular officers to adjudicate a BCC application. Section 41.32(a)(2), as contained in the interim regulation, has been amended to reflect this concept. The Department believes that this change does not significantly alter the substance or intent of the regulation and that it is, therefore, not necessary to open the change to public comment.

Photo Requirement

The interim rule, at section 41.42(a)(2)(ii), required that all applicants for the BCC provide one photograph of the size specified in the application, Form OF–156. This photo was to be used for record keeping purposes because it was not necessary for the production for the card itself. Because the BCC/NIV uses a digitized image on the card, the Department has decided it is no longer necessary for the applicant to submit a photo. This change has been reflected in the final regulation.

The remaining sections of the regulations were discussed in detail at **Federal Register** Public Notice 2773 and will be adopted as originally published, except for the minor changes indicated below.

The Regulatory Flexibility Act

Pursuant to sec. 605(b) of the Regulatory Flexibility Act, the Department has assessed the potential impact of this rule and it has been determined, and the Assistant Secretary for Consular Affairs hereby certifies, that it will not have a significant economic impact on a substantial number of small entities. The rule has no economic effect beyond that of the statutory requirements already in effect, which it implements.

5 U.S.C. Chapter 8

As required by 5 U.S.C. chapter 8, the Department has screened this rule and determined that it is not a major rule, as defined in 5 U.S.C. 80412.

Paperwork Reduction Act

The Department of State, Bureau of Consular Affairs, Visa Services has received OMB emergency clearance for the information collection instrument, Nonimmigrant Visa Application (OF–156), that underlies the nonimmigrant border crossing identification card (BCC) contained in this rule. It is estimated that 1,800,000 OF–156s will be completed annually to support the issuance of BCCs, and that (at 10 minutes per OF–156) this will require 300,000 hours of the time of aliens. Comments regarding OF–156 information collections in support of this rule should be identified as such and should be directed to Charles S. Cunningham, Directives Management Branch, U.S. Department of State, Washington, D.C. 20520, (202) 647–0596. Such comments should be received within 60 days of publication of this rule.

E.O. 12988 and E.O. 12866

This rule has been reviewed as required by E.O. 12988 and determined to meet the applicable regulatory standards it describes. Although exempted from E.O. 12866, this rule has been reviewed to ensure consistency with it.

List of Subjects in 22 CFR Part 41

Aliens, Nonimmigrants, Passports and visas, Temporary visitors.

Accordingly, the interim rule published on April 7, 1998 at 63 FR 16892 is adopted as final with the following changes:

PART 41—[AMENDED]

1. The authority citation for part 41 continues to read as follows:

Authority: 8 U.S.C. 1104.

2. Revise Section 41.32 to read as follows:

§ 41.32 Nonresident alien Mexican border crossing identification cards; combined border crossing identification cards and B–1/B–2 visitor visas.

(a) *Combined B–1/B–2 visitor visa and border crossing identification card (B–1/B–2 Visa/BCC).* (1) *Authorization for issuance.* Consular officers assigned to a consular office in Mexico designated by the Deputy Assistant Secretary for Visa Services for such purpose may issue a border crossing identification card, as that term is defined in INA 101(a)(6), in combination with a B–1/B–2 nonimmigrant visitor visa (B–1/B–2 Visa/BCC), to a nonimmigrant alien who:

(i) Is a citizen and resident of Mexico;

(ii) Seeks to enter the United States as a temporary visitor for business or pleasure as defined in INA 101(a)(15)(B) for periods of stay not exceeding six months;

(iii) Is otherwise eligible for a B–1 or B–2 temporary visitor visa or is the beneficiary of a waiver under INA 212(d)(3)(A) of a ground of ineligibility, which waiver is valid for multiple applications for admission into the United States and for a period of at least ten years and which contains no restrictions as to extensions of temporary stay or itinerary.

(2) *Procedure for application.* Mexican applicants shall apply for a B–1/B–2 Visa/BCC at any U.S. consular office in Mexico designated by the Deputy Assistant Secretary of State for Visa Services pursuant to paragraph (a) of this section to accept such applications. The application shall be submitted on Form OF–156. The application shall be supported by:

(i) Evidence of Mexican citizenship and residence;

(ii) The applicant's digitized photographic image taken at the time of the application; and

(iii) A valid Mexican Federal passport or a Certificate of Mexican Nationality (as long as the Certificate of Mexican Nationality is supported by another form of identification which includes a photograph) unless the applicant is the bearer of a currently valid or expired United States visa or BCC or B–1/B–2 Visa/BCC which has neither been voided by operation of law nor revoked by a consular or immigration officer. BCCs that, after October 1, 2001, or such other date as may be enacted, are no longer useable for entry due only to the absence of a machine readable biometric identifier shall not be considered to have been voided or revoked for the purpose of making an application under this section.

(iv) A digitized impression of the prints of the alien's index fingers taken at the time of the application.

(3) *Personal appearance.* Each applicant shall appear in person before a consular officer to be interviewed regarding eligibility for a visitor visa, unless the consular officer waives personal appearance.

(4) *Issuance and format.* A B–1/B–2 Visa/BCC issued on or after April 1, 1998, shall consist of a card, Form DSP–150, containing a machine-readable biometric identifier. It shall contain the following data:

(i) Post symbol;

(ii) Number of the card;

(iii) Date of issuance;

(iv) Indicia ''B–1/B–2 Visa and Border Crossing Card'';

(v) Name, date of birth, and sex of the person to whom issued; and

(vi) Date of expiration.

(b) *Validity.* A BCC previously issued by a consular officer in Mexico on Form I–186, Nonresident Alien Mexican Border Crossing Card, or Form I–586, Nonresident Alien Border Crossing Card, is valid until the expiration date on the card (if any) unless previously revoked, but not later than the date, currently October 1, 2001, on which a machine-readable, biometric identifier in the card is required in order for the card to be usable for entry. The BCC portion of a B–1/B–2 Visa/BCC issued to a Mexican national pursuant to provisions of this section contained in the 22 CFR, parts 1 to 299, edition revised as of April 1, 1998 is valid until the date of expiration, unless previously revoked, but not later than the date, currently October 1, 2001, on which a machine-readable, biometric identifier in the card is required in order for the card to be usable for entry.

(c) *Revocation.* A consular or immigration officer may revoke a BCC issued on Form I–186 or Form I–586, or a B–1/B–2 Visa/BCC under the provisions of § 41.122, or if the consular or immigration officer determines that the alien to whom any such document was issued has ceased to be a resident and/or a citizen of Mexico. Upon revocation, the consular or immigration officer shall notify the issuing consular or immigration office. If the revoked document is a card, the consular or immigration officer shall take possession of the card and physically cancel it under standard security conditions. If the revoked document is a stamp in a passport the consular or immigration officer shall write or stamp ''canceled'' on the face of the document.

(d) *Voidance.* (1) The voiding pursuant to INA 222(g) of the visa portion of a B–1/B–2 Visa/BCC issued at any time by a consular officer in Mexico under provisions of this section contained in the 22 CFR, parts 1 to 299, edition revised as of April 1, 1998, also voids the BCC portion of that document.

(2) A BCC issued at any time by a consular officer in Mexico under any provisions of this section contained in the 22 CFR, parts 1 to 299, edition revised as of April 1, 1998, is void if a consular or immigration officer determines that the alien has violated the conditions of the alien's admission into the United States, including the period of stay authorized by the Attorney General.

(3) A consular or immigration officer shall immediately take possession of a card determined to be void under paragraphs (d) (1) or (2) of this section

and physically cancel it under standard security conditions. If the document voided in paragraphs (d) (1) or (2) is in the form of a stamp in a passport the officer shall write or stamp ''canceled'' across the face of the document.

(e) *Replacement.* When a B–1/B–2 Visa/BCC issued under the provisions of this section, or a BCC or B–1/B–2 Visa/BCC issued under any provisions of this section contained in the 22 CFR, parts 1 to 299, edition revised as of April 1, 1998, has been lost, mutilated, destroyed, or expired, the person to whom such card was issued may apply for a new B–1/B–2 Visa/BCC as provided in this section.

3. Revise section 41.33 to read as follows:

§ 41.33 Nonresident alien Canadian border crossing identification card (BCC).

(a) *Validity of Canadian BCC.* A Canadian BCC or the BCC portion of a Canadian B–1/B–2 Visa/BCC issued to a permanent resident of Canada pursuant to provisions of this section contained in the 22 CFR, parts 1 to 299, edition revised as of April 1, 1998, is valid until the date of expiration, if any, unless previously revoked, but not later than the date, currently October 1, 2001, on which a machine readable biometric identifier is required in order for a BCC to be usable for entry.

(b) *Revocation of Canadian BCC.* A consular or immigration officer may revoke a BCC or a B–1/B–2 Visa/BCC issued in Canada at any time under the provisions of § 41.122, or if the consular or immigration officer determines that the alien to whom any such document was issued has ceased to be a permanent resident of Canada. Upon revocation, the consular or immigration officer shall notify the issuing consular office and if the revoked document is a card, the consular or immigration officer shall take possession of the card and physically cancel it under standard security conditions. If the revoked document is a stamp in a passport the consular or immigration officer shall write or stamp ''canceled'' on the face of the document.

(c) *Voidance.* (1) The voiding pursuant to INA 222(g) of the visa portion of a B–1/B–2 Visa/BCC issued at any time by a consular officer in Canada under provisions of this section contained in the 22 CFR, parts 1 to 299, edition revised as of April 1, 1998, also voids the BCC portion of that document.

(2) A BCC issued at any time by a consular officer in Canada under any provisions of this section contained in the 22 CFR, parts 1 to 299, edition revised as of April 1, 1998, is void if a consular or immigration officer finds that the alien has violated the conditions of the alien's admission into the United States, including the period of stay authorized by the Attorney General.

(3) A consular or immigration officer shall immediately take possession of a card determined to be void under paragraphs (c) (1) or (2) of this section and physically cancel it under standard security conditions. If the document voided under paragraphs (c) (1) or (2) is in the form of a stamp in a passport the officer shall write or stamp ''canceled'' across the face of the document.

Dated: August 10, 1999.

Mary A. Ryan,

Assistant Secretary for Consular Affairs.

[FR Doc. 99–21566 Filed 8–18–99; 8:45 am]

BILLING CODE 4710–06–U

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1610

RIN 3046–AA67

Availability of Records

AGENCY: Equal Employment Opportunity Commission (EEOC or Commission).

ACTION: Final rule.

SUMMARY: The Equal Employment Opportunity Commission is adopting as final without change an interim rule revising its Freedom of Information Act (FOIA) regulations to conform to the Electronic Freedom of Information Act Amendments of 1996, and to implement a delegation of the Regional Attorney's FOIA responsibilities, update office addresses and correct typographical errors.

EFFECTIVE DATE: This rule is effective on August 19, 1999.

FOR FURTHER INFORMATION CONTACT: Nicholas M. Inzeo, Deputy Legal Counsel, Thomas J. Schlageter, Assistant Legal Counsel, or Kathleen Oram, Senior Attorney, at (202) 663–4669 or TDD (202) 663–7026. This rule is also available in the following formats: large print, braille, audio tape and electronic file on computer disk. Requests for this rule in an alternative format should be made to EEOC's Publications Center at 1–800–669–3362.

SUPPLEMENTARY INFORMATION: On January 9, 1998, at 63 FR 1339–1342, the Equal Employment Opportunity Commission published an interim final rule implementing the Electronic Freedom of Information Act Amendments of 1996 (Public Law 105–231). The interim rule also revised the regulation to reflect a delegation of FOIA responsibilities by the Regional Attorneys, update field office addresses, and correct some typographical errors. Comments on the revisions were invited from the public, to be received by EEOC on or before March 10, 1998. No comments were received and EEOC has determined that no changes are needed to the interim rule. Therefore, EEOC is adopting the interim rule, without change, as final.

Regulatory Procedures

Regulatory Flexibility Act

The Commission, in accordance with the Regulatory Flexibility Act (5 U.S.C. 606(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant impact on a substantial number of small entities.

Executive Order 12866

This regulation has been reviewed in accordance with Executive Order 12866. The Office of Management and Budget has determined that this rule is not a ''significant regulatory action'' as defined in Executive Order 12866 because the revisions contained in this final rule incorporate only those changes required by the Electronic FOIA Amendments of 1996, a provision allowing regional attorneys to delegate their FOIA responsibilities, updated field office addresses, and corrections of typographical errors.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 29 CFR Part 1610

Freedom of information.

Accordingly, for the reasons set forth in the preamble, the Equal Employment Opportunity Commission is adopting the interim rule amending 29 CFR part 1610, which was published at 63 FR 1339–1342, on January 9, 1998, as a final rule without change.

For the Equal Employment Opportunity Commission.

Dated at Washington, DC, this 10th day of August, 1999.

Ida L. Castro,

Chairwoman.

[FR Doc. 99–21567 Filed 8–18–99; 8:45 am]

BILLING CODE 6570–01–M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 75

RIN 1219–AB10

Safety Standard for Preshift Examinations in Underground Coal Mines

AGENCY: Mine Safety and Health Administration, (MSHA) Labor.

ACTION: Final rule.

SUMMARY: We (MSHA) are amending the examination interval for preshift examinations of underground coal mines by requiring that mine operators conduct preshift examinations at 8-hour intervals. The rule clarifies when a preshift examination is required and the length of the shift covered by the preshift examination.

EFFECTIVE DATES: This final rule is effective on October 18, 1999. Submit all written comments on the information collection burden no later than October 18, 1999.

FOR FURTHER INFORMATION CONTACT: Carol J. Jones, Acting Director; Office of Standards, Regulations, and Variances; telephone 703/235–1910; fax 703/235–5551.

SUPPLEMENTARY INFORMATION:

I. Background

The preshift examination is the mine operator's fundamental tool for assessing the overall safety condition of the mine. During the preshift examination, which includes all areas where miners are scheduled to work or travel during the shift, the examiner focuses on discovering both existing and developing hazards, such as methane accumulation, bad roof and water accumulation, and determining the effectiveness of the mine ventilation system. The examination has proven to be particularly effective in the discovery and correction of hazardous conditions and practices before they lead to injuries or fatalities. Because conditions in the underground mining environment can change rapidly, recurring examinations are necessary to assure safety of the miners underground. A timely preshift examination assures the safety of the environment on a routine basis.

The Federal Mine Safety and Health Act of 1977 (Mine Act) contains interim mandatory safety standards that address preshift examinations. The interim standards in the Mine Act that relate to preshift examinations, §§ 303(d)(1) and 303(d)(2), appear as interim mandatory safety standards in the Federal Coal Mine Health and Safety Act of 1969. In 1970, the Bureau of Mines of the United States Department of the Interior, a predecessor of the Mine Safety and Health Administration at that time, adopted these interim standards as safety standards in Title 30 of the Code of Federal Regulations (CFR). Interim standard § 75.303(d)(1) required that preshift examinations be conducted ''[w]ithin three hours immediately preceding the beginning of any shift.'' We adopted this provision as a mandatory safety standard in our regulations for underground coal mines, promulgating it in 1978 as former 30 CFR 75.303(a).

Section 303(d)(2) of the Mine Act, the other interim standard addressing preshift examinations, provided that no person, other than certified persons designated to conduct the examination, is permitted to enter any underground area, except during any shift, unless a preshift examination of such area has been made within 8 hours prior to the person entering the area. Under this provision, miners already working on a shift where a preshift examination has been completed may remain working underground during the subsequent preshift examination being conducted for the oncoming shift. In 1978, MSHA adopted this provision as a mandatory safety standard in its regulations for underground coal mines as former 30 CFR § 75.303(b).

At the time the Mine Act was enacted, coal miners worked in shifts of 8 hours as a general practice. The effect of the preshift examination requirement in this environment was for examiners to conduct preshift examinations every 8 hours. Since the Mine Act was enacted, overlapping work shifts and work shifts of various lengths (novel work shifts) have become common, making it necessary for MSHA to address the frequency of preshift examinations. Currently, a number of mines work shifts of up to 12 hours in length.

In 1992, we revised our preshift examination requirements as part of our final rule for ventilation standards. We retained the requirement that preshift examinations must be conducted ''within 3 hours preceding the beginning of any shift.'' However, in our preamble discussion to the 1992 final ventilation rule, we interpreted this language to mean that if the mine used regular shifts longer than 8 hours, the preshift examination applied to the entire length of the shift (57 FR 20893).

In 1994, we proposed a new preshift examination rule in an attempt to clarify and standardize the application of certain provisions of the 1992 preshift examination rule (59 FR 26356). In the comments submitted to us during the 1994 rulemaking, a segment of the mining community expressed concern that because of novel work schedules, preshift examinations were not being conducted frequently enough to assure safe working conditions. A commenter expressed concern that conducting preshift examinations at intervals longer than 8 hours would reduce the protection afforded miners under the Mine Act. The commenter also stated that MSHA introduced confusion into the preshift examination requirements in interpreting the acceptable intervals for preshift examinations.

Another segment of the public argued that the language of § 303(d)(2) of the Mine Act indicates that Congress tacitly accepted shifts longer than 8 hours with only one preshift examination required. The same segment of the public argued that we allowed a practice to evolve over a period of time which permitted not only longer shifts but also ''excursions'' over 8 hours under specific conditions. During these so-called excursions, miners would remain underground for short periods to handle unplanned situations that developed during the shift. As an example, an excursion might be used to perform mechanical repairs or install roof support. Finally, commenters representing both labor and industry recommended that we adopt a final rule requiring preshift examinations for each 8-hour period that miners are underground.

When we promulgated the 1994 proposed rule as a final rule in 1996, (61 FR 9764) we addressed the comments and revised the existing standard. We substituted the phrase ''8-hour interval'' for the phrase ''beginning of any shift.'' The 1996 rule required a preshift examination, ''* * * within 3 hours preceding the beginning of any 8-hour interval during which any person is

scheduled to work or travel underground. * * *'' We also acknowledged in the preamble to the final rule that, in accordance with longstanding practice, unplanned short excursions past the 8-hour period that occur infrequently are accepted without an additional preshift examination (61 FR 9791).

In the preamble to the 1996 final rule, we discussed our rationale for adopting an 8-hour preshift examination rule. We stated that:

> Underground working schedules of three 8-hour shifts per day were virtually standard when the previous rule was implemented. Currently a substantial number of mining operations have work shifts of more than 8 hours. Other operations stagger or overlap shifts providing for continuous underground mining activities. Some mines that operate around the clock schedule persons to begin shifts at one-or two-hour intervals. In such cases, controversies and misunderstandings have developed regarding application of the current standard. . . . MSHA agrees with commenters that evolution within the industry in shift scheduling has presented a number of questions and controversies regarding the standard which must be resolved to assure that proper preshift examinations are conducted within suitable time frames. Based on comments, the final rule adopts a modification to clarify and standardize the application of the preshift examination in recognition of the use of novel shifts while maintaining the protection of the existing standard. (61 FR 9791).

In adopting an 8-hour preshift examination requirement, we agreed with comments suggesting that the original legislation of the Mine Act envisioned that preshift examinations would be conducted for each 8-hour interval that persons worked underground'' (61 FR 9791). We reached this conclusion both from the traditional practice at the time of the legislation and from the language of § 303(d)(2) of the Mine Act.

On June 17, 1997, the United States Court of Appeals for the District of Columbia Circuit, in *National Mining Association* v. *Mine Safety and Health Administration and Secretary of Labor (MSHA),* 116 F.3d 520 (D.C. Cir. 1997), acknowledged that the approach used by MSHA in adopting the 8-hour interval for the preshift examination was a reasonable one. The Court stated, ''At the least, 30 CFR § 75.360(a)(1) is a reasonable interpretation of open-ended statutory language.* * * We see no reason why we should not think of 30 CFR § 75.360(a)(1) as just such an ''improved mandatory safety standard'' issued in light of changed circumstances in the mining industry.'' (116 F.3d 520, 530). However, the Court invalidated the provision on the procedural ground that we failed to provide sufficient notice to the parties in the rulemaking that we were contemplating requiring a preshift examination every 8 hours. The effect of the decision was to reinstate the portion of the previous standard that requires a preshift examination to be conducted prior to the beginning of any shift. We published a **Federal Register** notice on June 30, 1997 (62 FR 35085) conforming the language of the existing standard to the Court's order.

On July 14, 1998, in response to the Court's *National Mining Association* decision, we published a proposed rule addressing the existing preshift examination requirements (63 FR 38066). Instead of requiring a preshift examination at the beginning of each shift, the Agency proposed that a preshift examination be conducted at 8-hour intervals. Specifically, we proposed:

> *§ 75.360 Preshift examination at fixed intervals.*
>
> (a)(1) Except as provided in paragraph (a)(2) of this section, a certified person designated by the operator shall make a preshift examination within 3 hours preceding the beginning of any 8-hour interval during which any person is scheduled to work or travel underground. No person other than certified examiners may enter or remain in any underground area unless a preshift examination has been completed for the established 8-hour interval. The operator shall establish 8-hour intervals of time subject to the required preshift examinations. (63 FR 38071).

In the preamble to the proposed rule, we stated, ''MSHA continues to believe that it is necessary to address the issues surrounding the preshift examination interval. The standard must provide for sufficient protection, be clear in its recommendations, and be properly implemented to ensure safe working conditions in underground coal mines'' (63 FR 38068).

II. Discussion of § 75.360(a)(1)

The final rule modifies existing § 75.360(a)(1) to require preshift examinations at fixed 8-hour intervals. The final rule is substantively identical to the proposed rule. The word ''shall'' is changed to ''must'' in the final rule in accordance with the style advocated by the President's Memorandum on Plain Language. Existing § 75.360(a)(1) provides:

> Except as provided in paragraph (a)(2) of this section, a certified person designated by the operator shall make a preshift examination within 3 hours preceding the beginning of any shift during which any person is scheduled to work or travel underground. No person other than certified examiners may enter or remain in any underground area unless a preshift examination has been completed for the shift.

The rule replaces the word ''shift'' with the phrase ''8-hour interval''. In addition, the rule adds the sentence, ''The operator must establish the 8-hour intervals of time subject to the required preshift examinations.'' The final rule advances the overall safety at underground coal mines and does not reduce the protection afforded by the existing standard.

Considering the speed at which underground conditions can change, preshift examinations are necessary after a reasonable but defined period of time. As an example, methane, an explosive gas naturally occurring in coal mines, commonly builds up over time, especially in newly mined areas. Methane may also accumulate in other areas, such as where water accumulation interferes with mine ventilation. A preshift examination should result in the detection of this explosive gas, if present, and the timely correction of the condition before it reaches a hazardous level. Also, the roof and ribs tend to deteriorate over time throughout the mine, including outby entries used as travelways and on the sections of a mine where miners are assigned to work. Roof pressures and subsequent falls can damage ventilation controls, resulting in hazardous conditions. Equipment damaged by a roof fall, including belt haulage systems or trolley wire systems, can lead to mine fires or explosions. A preshift examination provides a mechanism to detect these developing hazards.

We have reviewed the history of fatalities that have occurred at underground coal mines since 1990 to determine if any of the fatalities occurred more than 8 hours after the start of the shift and, therefore, may have been prevented had the proposed rule been in place. We placed in the rulemaking record 32 fatal accident reports of MSHA investigations conducted since 1990. In each report the accident was identified as occurring more than 8 hours into the shift. At least 6 of the reports, representing 7 fatalities, address instances where an additional preshift examination might have identified the hazards that resulted in the fatalities and allowed an opportunity for corrective action. The accidents are: Linda Enterprise, Inc., #31–A mine, March 23, 1990, 1 fatality; Miller Branch Enterprises, Inc., No. 1 mine, December 4, 1991, 1 fatality; M.A.G. Incorporated, Alloy Deep Mine ι2, October 2, 1993, 1 fatality; Day Branch Coal Co., Inc., No. 9 mine, May 11, 1994, 2 fatalities; Waco Limited

Partnership No. 1, No. 2 mine, December 18, 1995, 1 fatality; and M&D Coal Co., Inc., No. 3 mine, August 15, 1996, 1 fatality. We note that the rule being finalized was in effect between June 1996 and July 1997. However, the rule was not being followed at the M&D No. 3 mine at the time of the August 15, 1996, accident.

The final rule applies to all underground coal mines, including those that operate with only one 8-hour shift per day. If the mine uses regular shifts that are longer than 8 hours in length, the preshift examination would cover an 8-hour interval; an additional examination is required for over 8 hours. The rule requires three preshift examinations where persons are underground for more than 16 hours per day. As an example, at a mine operating two 10-hour shifts per day, the final rule requires three examinations per day. As with the existing standard, the final rule does not require examinations for designated 8-hour periods when no one enters the mine. Also consistent with the existing standard, no one, except other designated preshift examiners, may accompany preshift examiners during an examination before miners reenter the mine.

Once a preshift examination has been conducted, an additional preshift examination is not necessary during the 8-hour interval covered by the preshift examination simply because persons start to work after the beginning of the normal shift start time. Under the final rule persons can enter or leave the mine, regardless of their shift schedule, during any established 8-hour period for which a preshift examination has been conducted. However, another preshift examination must be completed prior to the beginning of the next 8-hour interval if any persons, other than examiners, remain in the mine during the next 8-hour interval or are scheduled to enter the mine during the oncoming interval. As with the existing standard, no person other than examiners may enter any underground area that is subject to a preshift examination prior to the completion of the preshift examination for that area. Also, supplemental examinations continue to be required under § 75.361 before anyone enters areas of the mine that have not had a preshift examination. In accordance with prior practice, miners already working on a shift for which a preshift examination has been completed may remain working underground during the subsequent preshift examination being conducted for the oncoming shift.

We recognize that the final rule may cause some of the mine operators to perform additional examinations that are not currently required. As an example, some small mines operate 1 shift per day. Many of these mines plan to work 8 hours at the face. Allowing for travel time and lunch, the mines may work a single 8½ or 9 hour shift on a regular basis. Under the final rule, 2 preshift examinations are required.

In the preamble to the proposed rule, we encouraged all parties to express their views fully on the proposal and submit comments on the proposed preshift examination rule. Also, we specifically solicited comments in a number of areas, such as whether excursions should be permitted, and the safety benefits gained by requiring a mine that operates a single 8½ or 9 hour shift per day to conduct 2 preshift examinations.

We received comments from a total of 4 commenters: 2 mining associations, 1 mining company, and 1 labor organization. One commenter advocated MSHA's approach of conducting a preshift examination at 8-hour intervals, stating that Congress intended preshift examinations to be conducted at 8-hour intervals, that it is essential that the requirements for preshift examinations be clear and unambiguous, and that the issue of the frequency of preshift examinations is vitally important for safety and health. This commenter opposed any excursions beyond the 8-hour interval except for life threatening situations. The other 3 commenters stated that we must be more flexible in our approach to determining preshift examination intervals. Two commenters stated that mine plans should incorporate preshift examination requirements specific to each mine. Three commenters pointed out that because of State laws, there are instances where additional and unnecessary preshift examinations are required. These commenters favored a preshift examination that covered an entire shift, regardless of its duration. Two of the commenters pointed out that technological advances, such as mine-wide monitoring systems used in some mines, have made mines safer than they were at the time Congress passed the Mine Act. Two commenters stated that many examinations occur during a shift. Consequently, these commenters felt that preshift examinations that lasted the duration of the shift, whether 8, 10, or 12 hours, should be acceptable in mines using technological advances such as mine-wide monitoring systems.

We have carefully considered each of the comments and have determined that, with minor non-substantive changes, it is appropriate to adopt and publish the proposed rule as the final rule. The Agency has concluded that, considering the speed at which the underground conditions can change, there must be a defined, reasonable period after which another examination is necessary. The history of fatalities at underground mines since 1990 demonstrates that as many as 7 lives could have been saved if the 8 hour interval rule had been in place. As one commenter stated, repeating language from the preamble to the proposed rule:

> [t]he preshift examination is a critically important, fundamental safety practice in the mining industry. It has historically been a primary means of determining the effectiveness of an underground coal mining operation, and of detecting hazardous conditions and practices. The preshift examination has proven to be particularly effective because it provides a thorough safety check before work commences underground on the shift for which the examination is conducted. A preshift examination can detect developing hazards as well as existing hazards.

The preshift examination at 8-hour intervals is a clear and easily understood requirement that has an historical basis in legislative history. We are not persuaded by commenters that, due to technological improvements in modern mining as well as the training that modern miners receive, there is a need to deviate from the frequency of preshift examinations envisioned by Congress. The fact that mines may be somewhat safer today than they were in the past does not change the fact that the hazards still exist. Miners and operators must be vigilant in dealing with methane accumulation, roof and rib deterioration and water accumulation, as well as other hazards. Progress in safety due to modern mining and monitoring systems has not lessened the need for preshift examinations at 8-hour intervals, which we believe will result in increased miner safety. As we have noted previously, we have identified 7 fatalities that might have been prevented if preshift examinations had occurred at 8-hour intervals. Technological advances that enhance safety, such as atmospheric monitoring systems, should supplement the proper use of preshift examinations rather than change the frequency of the examination.

Through a longstanding practice, we have permitted excursions beyond the normal scheduled shift for preshift examinations. In this final rule, we will permit miners to stay on the section or in the work area for up to an additional 15 minutes beyond an 8-hour shift to conclude the mining cycle at an appropriate point, perform mechanical repairs, install roof support, or as a

result of a mantrip delay. We will continue to interpret the final rule to allow such excursions. One commenter addressed this issue. The commenter to the proposed rule objected to any excursion except for life-threatening situations. The commenter added that, to prevent abuse, if other excursions are permitted, the rule should be specific in defining the circumstances under which excursions are permitted. We agree with the commenter that an excursion for a life-threatening situation does not require an additional preshift examination. We also believe that there are good reasons for excursions for other circumstances: a machinery breakdown which requires miners to walk from the mine, or a roof control problem requiring immediate attention before the miners leave the mine. Some flexibility is appropriate to account for unanticipated circumstances. We continue to believe that short excursions of up to 15 minutes should be permitted. Also, an infrequent excursion of up to 30 minutes is acceptable under an unanticipated circumstance such as a mechanical breakdown. While, by their nature, these infrequent excursions are unpredictable, we expect that excursions would be necessary on the average of no more than once a week.

Two commenters recommended that the rule should provide enough flexibility to improve safety and provide a better utilization of resources. The commenters gave an example of an operator who has established 3-hour intervals spaced 8 hours apart to preshift examine the face areas of the mine. According to these commenters, the same operator at the same mine should be able to examine belts, travelways, and other areas during another, different series of 3-hour intervals spaced 8 hours apart. We agree that this is an acceptable flexible approach that does not diminish safety. The final rule permits this approach. However, we note that after an idle period, a full preshift examination must be completed before miners reenter the area.

We received 2 comments which suggested that the mine ventilation plan could be used to provide for flexibility in scheduling preshift examinations, particularly in cases where an inconsistency might exist with State requirements for examinations. These commenters favored a preshift examination that covered an entire shift regardless of its duration. We believe that a uniform requirement for an examination every 8 hours best serves the purposes of miner safety and health. Use of the plan approval process to essentially adopt a longer preshift examination interval would not be appropriate.

A commenter pointed out that the Pennsylvania Bituminous Coal Mine Act requires a preshift examination in a gassy mine within the 3 hours immediately preceding the beginning of a coal-producing shift. The commenter stated that there are currently 2 mines in Pennsylvania that work 2 shifts of 12 hours, and these only on weekends. Considering the interaction of the MSHA and the Pennsylvania rules, these mines and possibly several others in Pennsylvania, may be required to conduct 4 preshift examinations instead of the 3 examinations otherwise conducted during a 24 hour period. We believe that the requirement for preshift examinations at 8 hour intervals is appropriate and do not believe that the hazardous environment in underground coal mines allows for an exemption in this case. In addition, the history of fatalities that have occurred since 1990 in shifts longer than 8 hours does not support a preshift examination at 12 hour intervals.

Another commenter stated that the proposed preshift requirement would adversely impact safety by requiring the section foreman, supervising a production crew, to examine outby areas during production shifts in excess of 8 hours. The safety of the production crew at the face would be unmonitored during this time. This situation might arise in a 1-shift mine with a single certified person onsite. We agree that in this circumstance, having the foreman on the section and available to supervise the production crew provides a safety benefit. However, we also believe that an examination of outby areas is necessary to assure that any hazardous conditions are identified and corrected in a timely manner. When an additional preshift examination is necessary, the on-section portion of the examination can be conducted concurrently with the on-shift examination. Any certified person designated by the operator may conduct the examination of the outby areas and a vehicle can be used to expedite the examination and to minimize any absence from the section. Also, in such a circumstance, we will accept an examination of outby areas by the certified person during egress from the mine where the examiner travels ahead of the crew, examining while traveling. If a hazard is encountered, the examiner must be able to stop the crew before they reach the hazard. This approach preserves the certified person's presence on the section during the work period and provides for the outby portion of the examination before miners travel through the area. We note that this is only applicable before an idle period. If a crew is scheduled to enter the area, a preshift examination must be completed before the next 8-hour interval begins.

For accuracy, we are changing the title of § 75.360 from ''Preshift examination'' to ''Preshift examination at fixed intervals.'' The text of the final rule and the preamble discussion of the standard continue to refer to the examination as the ''preshift examination.'' Because of the history of the term and the widespread understanding in the industry of the safety checks required by a preshift examination, we are continuing to use the term ''preshift examination'' in the body of the standard and to refer to the examination as the preshift examination.

III. Paperwork Reduction Act

This final rule contains an information collection requirement which is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA 95). It is identical to the information collection requirement in our proposed rule. We did not receive any comments on the proposed information collection requirement. OMB has approved the information collection requirement and assigned to it OMB control number 1219–0125. The approval expiration date is October 31, 2001.

IV. Executive Order 12866 Regulatory Planning and Review

Executive Order (EO) 12866 requires that agencies assess both the costs and benefits of intended regulations. We have determined that this rule would not have an annual effect of $100 million or more on the economy and, therefore, that this rulemaking is not a significant regulatory action for purposes of this EO. Although the final rule applies to all underground coal mines, it will cause 127 underground coal mines to incur compliance costs (or approximately 13 percent of all underground coal mines). Of the 127 mines, 75 are small mines (mines with fewer than 20 employees), and 52 are large mines (mines with 20 or more employees). The total estimated annual compliance cost of the final rule is $2,218,731. Small and large underground coal mines will have annual compliance costs of $377,192 and $1,841,539, respectively.

The total 1997 revenues for the underground coal mine industry are estimated to be about $7.6 billion. The final rule's estimated annual cost is less than 0.03 percent of annual estimated

revenues for all mines (all underground coal mines) which are covered by the rule. We do not expect this rule to have a significant economic impact on the underground coal mining industry.

V. Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act (SBREFA)

Under SBREFA, in analyzing the impact of a final rule on small entities, MSHA must use the Small Business Administration (SBA) definition for a small entity or, after consultation with the SBA Office of Advocacy, establish an alternative definition for the mining industry by publishing that definition in the **Federal Register** for notice and comment. We have not taken such an action and, therefore, are required to use the SBA definition. MSHA traditionally has considered small mines to be those with fewer than 20 employees. The SBA defines a small mining entity as an establishment with 500 or fewer employees (13 CFR 121.201). Almost all underground coal mines fall into this category. For these small underground coal mines, as defined by SBA, we conducted a screening analysis by comparing their estimated cost of complying with the final rule to their estimated revenues. When estimated compliance costs are less than 1 percent of estimated revenues, we believe it is generally appropriate to conclude that there is no significant economic impact on a substantial number of small entities. When estimated compliance costs exceed 1 percent of estimated revenues, it tends to indicate that further analysis may be warranted. We estimate compliance costs for small underground coal mines covered under this rule (using the SBA definition) to be $2,182,721 and their revenues to be approximately $6.916 billion (as shown on Table 1). Therefore, the costs of complying with the final rule for small underground coal mines are approximately 0.03 percent of their estimated revenues.

With respect to this final rule, 126 of the 127 underground coal mines that will incur compliance costs fall under SBA's definition. When the 126 underground coal mines that are immediately affected by this rule are separately considered, the costs of complying with the final rule for such mines are 0.3 percent of their revenues (as shown on Table 2).

In either case, the rule's costs as a percentage of estimated revenues are well below the 1 percent level. Accordingly, we certify that the final rule will not have a significant impact on a substantial number of small entities (mines with 500 or fewer employees).

TABLE 1.—ESTIMATED REVENUES OF UNDERGROUND COAL MINES COVERED BY THE RULE

Mine size (employees)	Number of mines [a]	Average production per mine (tons) [a]	Total estimated revenues (in millions) [b]
≤ 500	959	398,221	$6,916
> 500	9	4,196,324	684
Total	968		7,600

[a] Sources: Based on MSHA's database and MSHA's CM441 Coal Report 1997 cycle 1997/184.
[b] Total revenues = n x t x p, where n is the number of mines in that size class; t is the average tons of coal produced annually by a mine in that size class; and p is the price per ton of coal. The 1997 price per ton of coal was $18.11 (Source: DOE/EIA *Annual Energy Review,* p. 203).

TABLE 2.—ESTIMATED REVENUES FOR UNDERGROUND COAL MINES AFFECTED BY THE RULE

Mine size (employees)	Number of mines [a]	Average production per mine (tons) [a]	Total estimated revenues (in millions) [b]
< 20	75	33,304	$45
> 20 & < 500	51	689,881	637
Total	126		682

[a] Based on MSHA's CM441 Coal Report 1997 cycle 1997/184.
[b] Total revenues n x t x p, where n is the number of mines in that size class; t is the average tons of coal produced annually by a mine in that size class; and p is the price per ton of coal. The 1997 price per ton of Coal was $18.11 (Source: DOE/EIA *Annual Energy Review,* p. 203).

VI. Executive Order 12875 Enhancing the Intergovernmental Partnership; and the Unfunded Mandates Reform Act of 1975

Executive Order (EO) 12875 requires executive agencies and departments to reduce unfunded mandates on State, local, and tribal governments; to consult with these governments prior to promulgation of any unfunded mandate; and to develop a process that permits meaningful and timely input by State, local, and tribal governments in the development of regulatory proposals containing a significant unfunded mandate. EO 12875 also requires executive agencies and departments to increase flexibility for State, local, and tribal governments to obtain a waiver from Federal statutory or regulatory requirements.

We offered governments an opportunity to provide meaningful and timely input, at the proposed rule stage, through the promulgation of the proposal for notice and comment. No state, local government or tribal government commented or requested a waiver of regulatory requirements.

Much of the Unfunded Mandates Reform Act of 1995 is designed to assist the Congress in determining whether its actions will impose costly new mandates on State, local, and tribal governments. It also includes requirements to assist Federal agencies to make this same determination with respect to regulatory actions.

We have determined that, for purposes of § 202 of the Unfunded Mandates Reform Act of 1995, this final rule does not include any Federal mandate that may result in increased expenditures by State, local, or tribal governments in the aggregate of more than $100 million, or increased expenditures by the private sector of more than $100 million. Moreover, we have determined that for purposes of § 203 of that Act, this final rule does not significantly or uniquely affect these entities.

We have prepared an estimate of the cost of the rule in our submission to OMB for approval of the information collection requirements in the rule. We will furnish a copy of this estimate to you upon request. A summary of the cost is contained in the preamble to this rule.

VII. Executive Order 13045 Protection of Children from Environmental Health Risks and Safety Risks

In accordance with Executive Order 13045, we have evaluated the environmental health or safety effect of the rule on children. We have determined that the rule will have no effect on children.

VIII. Executive Order 13084 Consultation and Coordination with Indian Tribal Governments

We certify that the final rule does not impose substantial direct compliance costs on Indian tribal governments. Further, we provided the public, including Indian tribal governments which operated mines, the opportunity to comment during the proposed rule's comment period. No Indian tribal government applied for a waiver or commented on the proposal.

IX. Executive Order 12612 Federalism

Executive Order 12612 requires that agencies, to the extent possible, refrain from limiting state policy options, consult with states prior to taking any action which would restrict state policy options, and take such actions only when there is a clear constitutional authority and the presence of a problem of a national scope. Since this rule does not limit state policy options, it complies with the principles of federalism and with Executive Order 12612.

X. Executive Order 12630 Government Actions and Interference with Constitutionally Protected Property Rights

This rule is not subject to Executive Order 12630 because it does not involve implementation of a policy with taking implications.

XI. Executive Order 12988 Civil Justice Reform

The Agency has reviewed Executive Order 12988 and determined that this rulemaking will not unduly burden the Federal court system. The regulation has been written to so as to provide a clear legal standard for affected conduct, and has been reviewed carefully to eliminate drafting errors and ambiguities.

List of Subjects

30 CFR Part 75

Mine safety and health, underground coal mining, ventilation.

Dated: August 11, 1999.

Marvin W. Nichols Jr.,

Deputy Assistant Secretary for Mine Safety and Health.

Accordingly, 30 CFR, chapter I, is amended as follows:

PART 75—MANDATORY SAFETY STANDARDS—UNDERGROUND COAL MINES

1. The authority citation for part 75 continues to read as follows:

Authority: 30 U.S.C. 811.

2. In subpart D of Part 75, the section heading of § 75.360 and paragraph (a)(1) are revised to read as follows:

§ 75.360 Preshift examination at fixed intervals.

(a)(1) Except as provided in paragraph (a)(2) of this section, a certified person designated by the operator must make a preshift examination within 3 hours preceding the beginning of any 8-hour interval during which any person is scheduled to work or travel underground. No person other than certified examiners may enter or remain in any underground area unless a preshift examination has been completed for the established 8-hour interval. The operator must establish 8-hour intervals of time subject to the required preshift examinations.

* * * * *

[FR Doc. 99–21448 Filed 8–18–99; 8:45 am]

BILLING CODE 4510–43–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 009–0143a; FRL–6420–4]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revisions for Six California Air Pollution Control Districts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the California State Implementation Plan (SIP) which concern the control of particulate matter (PM) emissions from open burning, incinerator burning, and orchard heater sources in the Kern County Air Pollution Control District (KCAPCD), Northern Sierra Air Quality Management District (NSAQMD), San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD), Siskiyou County Air Pollution Control District (SCAPCD), Tehama County Air Pollution Control District (THCAPCD), and Tuolumne County Air Pollution Control District (TOCAPCD). This approval action will incorporate these rules into the federally-approved SIP. The intended effect of this action is to regulate emissions of PM in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA). Thus, EPA is finalizing the approval of these rules 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 attainment and nonattainment areas.

DATES: This rule is effective on October 18, 1999 without further notice, unless EPA receives relevant adverse comments by September 20, 1999. If EPA receives such comments, then it will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Comments must be submitted to Andrew Steckel at the Region IX office listed below. Copies of the rules and EPA's evaluation report for the rules are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rules are available for inspection at the following locations:

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

Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, SW, Washington, DC 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812.

Kern County Air Pollution Control District, 2700 ''M'' Street, Suite 290, Bakersfield, CA 93301.

Northern Sierra Air Quality Management District, 540 Searles Avenue, Nevada City, CA 95959.

San Joaquin Valley Unified Air Pollution Control District, 1990 East Gettysburg Street, Fresno, CA 93726.

Siskiyou County Air Pollution Control District, 525 South Foothill Drive, Yreka, CA 96097.

Tehama County Air Pollution Control District, 1760 Walnut Street, Red Bluff, CA 96080.

Tuolumne County Air Pollution Control District, 2 South Green Street, Sonora, CA 95370.

FOR FURTHER INFORMATION CONTACT: Al Petersen, Rulemaking Office, (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1135.

SUPPLEMENTARY INFORMATION:

I. Applicability

The rules being approved into the California Applicable SIP are listed below with the date that they were submitted to EPA by the California Air Resources Board (CARB):

- KCAPCD Rule 416, Open Burning (submitted on October 18, 1996).
- KCAPCD Rule 417, Agricultural Burning (submitted on October 18, 1996).
- NSAQMD Rules 302 to 312, Open Burning (submitted on October 25, 1991).
- SJVUAPCD Rule 4302, Incinerator Burning (submitted on May 24, 1994).
- SJVUAPCD Rule 4303, Orchard Heaters (submitted on May 24, 1994).
- SCAPCD Rule 4.3, Non-Agricultural Burning (submitted on March 26, 1990).
- THCAPCD Rule 3.12, Wildland Vegetation Management Burning (submitted on May 13, 1991).
- TOCAPCD Rules 302 to 310, Open Burning (submitted on March 26, 1990).

II. Background

On March 3, 1978, EPA promulgated a list of total suspended particulate (TSP) nonattainment areas under the provisions of the 1977 Clean Air Act, that included the San Joaquin Valley Air Basin (43 FR 8964; 40 CFR 81.305). On July 1, 1987 (52 FR 24672) EPA replaced the TSP standards with new PM standards applying only to PM up to 10 microns in diameter (PM–10).[1] On November 15, 1990, amendments to the 1977 CAA were enacted (Pub. L. 101–549, 104 Stat. 2399, codified at 42 U.S.C. *7401–7671q*). On the date of enactment of the 1990 CAA Amendments, PM–10 areas meeting the qualifications of section 107(d)(4)(B) of the Act were designated nonattainment by operation of law and classified as moderate or serious pursuant to section 188(a). Nevada County, Plumas County, and Sierra County (all of which now comprise NSAQMD), Siskiyou County, Tehama County, and Tuolumne County were designated unclassifiable for PM–10. The present KCAPCD includes a part of Kern County, which was designated unclassifiable for PM–10, and a part of Searles Valley, which was classified and designated moderate nonattainment for PM–10. On February 8, 1993, EPA classified four nonattainment areas as serious, including the San Joaquin Valley Planning Area, which now comprises the SJVUAPCD.

Section 189(a) of the CAA requires PM–10 moderate nonattainment areas to adopt reasonably available control measures (RACM), including reasonably available control technology (RACT) for stationary sources of PM–10. Section 189(b) of the CAA requires PM–10 serious nonattainment areas to adopt best available control measures (BACM) for significant sources of PM–10, including best available control technology (BACT).

KCAPCD must adopt RACM due to including the Searles Valley Planning Area PM–10 moderate non-attainment area. However, the ''PM–10 SIP for the Searles Valley Planning Area'', pg III.6, November 1991, shows that the PM–10 Emissions Inventory is zero for waste (open) burning. Therefore, adopting RACM would not decrease emissions, and KCAPCD will not be evaluated by RACM requirements.

SJVUAPCD must at a minimum meet the requirements of RACM; SJVUAPCD must also meet the requirements of BACM. However, EPA is deferring decision on the specific BACM requirements until EPA acts on SJVUAPCD's BACM plan at a later date.

In response to section 110(a) and Part D of the Act, the State of California submitted many PM–10 rules for incorporation into the California SIP, including the rules being acted on in this document. This document addresses EPA's direct-final action for the following:

- KCAPCD Rule 416, Open Burning.

This rule was amended by the KCAPCD on July 11, 1996, submitted by the CARB for incorporation into the California SIP on October 18, 1996, and found to be complete on December 19, 1996, pursuant to EPA's completeness criteria that are set forth in 40 CFR part 51 appendix V[2] and is being finalized for approval into the SIP.

- KCAPCD Rule 417, Agricultural Burning.

This rule was amended by the KCAPCD on July 11, 1996, submitted by the CARB for incorporation into the California SIP on October 18, 1996, and found to be complete on December 19, 1996.

- NSAQMD Rule 302, Prohibited Open Burning.
- NSAQMD Rule 303, Allowed Open Burning.
- NSAQMD Rule 304, Agricultural Burning.
- NSAQMD Rule 305, Range Improvement Burning.
- NSAQMD Rule 306, Forest Management Burning.
- NSAQMD Rule 307, Wildlands Vegetation Management Burning.
- NSAQMD Rule 308, Land Development Clearing.
- NSAQMD Rule 309, Ditch, Road and Right-of-FyWay Maintenance.
- NSAQMD Rule 310, Hazard Reduction.
- NSAQMD Rule 311, Residential Maintenance.
- NSAQMD Rule 312, Burning Permits.

These rules were adopted by the NSAQMD on November 10, 1988, submitted by the CARB for incorporation into the California SIP on October 25, 1991, and found to be complete on December 18, 1991.

- SJVUAPCD Rule 4302, Incinerator Burning. This rule was initially adopted by the SJVUAPCD on May 21, 1992, amended by the SJVUAPCD on December 16, 1993, submitted by the CARB for incorporation into the California SIP on May 24, 1994, and found to be complete on July 14, 1994.
- SJVUAPCD Rule 4303, Orchard Heaters. This rule was initially adopted by the SJVUAPCD on May 21, 1992, amended by the SJVUAPCD on December 16, 1993, submitted by the CARB for incorporation into the California SIP on May 24, 1994, and found to be complete on July 14, 1994.
- SCAPCD Rule 4.3, Non-Agricultural Burning. This rule was initially adopted by the SCAPCD on October 26, 1971, amended by the SCAPCD on January 24, 1989, submitted by the CARB for incorporation into the California SIP on March 26, 1990, and found to be complete on June 20, 1990.

[1] On July 18, 1997 EPA promulgated revised and new standards for PM–10 and PM–2.5 (62 FR 38651). The U.S. Court of Appeals for the D.C. Circuit in American Trucking Assoc., Inc., *et al.* v. *USEPA*, No. 97–1440 (May 14, 1999) issued an opinion that, among other things, vacated the new standards for PM–10 that were published on July 18, 1997 and became effective September 16, 1997. However, the PM–10 standards promulgated on July 1, 1987 were not an issue in this litigation, and the Court's decision does not affect the applicability of those standards in this area. Codification of those standards continue to be recorded at 40 CFR 50.6. In the notice promulgating the new PM–10 standards, the EPA Administrator decided that the previous PM–10 standards that were promulgated on July 1, 1987, and provisions associated with them, would continue to apply in areas subject to the 1987 PM–10 standards until certain conditions specified in 40 CFR 50.6(d) are met. See 62 FR 38701. EPA has not taken any action under 40 CFR 50.6(d) for this area. Today's proposed action relates only to the CAA requirements concerning the PM–10 standards as originally promulgated in 1987.

[2] EPA adopted the completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to section 110(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

• THCAPCD Rule 3.12, Wildland Vegetation Management Burning. This rule was initially adopted by the THCAPCD on August 4, 1987, amended by the THCAPCD on April 25, 1989, submitted by the CARB for incorporation into the California SIP on May 13, 1991, and found to be complete on July 10, 1991.

• TOCAPCD Rule 302, Burning Requirements.

• TOCAPCD Rule 303, Burn or No-Burn Day.

• TOCAPCD Rule 304, Burning Management Requirements.

• TOCAPCD Rule 305, Minimum Drying Times.

• TOCAPCD Rule 306, Agricultural Burning.

• TOCAPCD Rule 307, Wildland Vegetation Management.

• TOCAPCD Rule 308, Forest Management.

• TOCAPCD Rule 309, Range Improvement.

• TOCAPCD Rule 310, Miscellaneous Burning.

These rules were adopted by the TOCAPCD on November 22, 1988, submitted by the CARB for incorporation into the California SIP on March 26, 1990, and found to be complete on June 20, 1990.

PM emissions can harm human health and the environment. These rules were adopted as part of KCAPCD, NSAQMD, SJVUAPCD, SCAPCD, THCAPCD, and TOCAPCD efforts to maintain the National Ambient Air Quality Standard (NAAQS) for PM–10. The following is EPA's evaluation and final action for these rules.

III. EPA Evaluation and Action

In determining the approvability of a PM–10 rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and part D of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). EPA must also ensure that rules are enforceable and strengthen or maintain the SIP's control strategy.

The statutory provisions relating to RACM/RACT and BACM/BACT are discussed in EPA's ''General Preamble'', which give the Agency's preliminary views on how EPA intends to act on SIPs submitted under Title I of the CAA. See 57 FR 13498 (April 16, 1992), 57 FR 18070 (April 28, 1992) and 59 FR 41998 (August 16, 1994). In this rulemaking action, EPA is applying these policies to this submittal, taking into consideration the specific factual issues presented.

EPA previously reviewed rules from KCAPCD, NSAQMD, SJVUAPCD, SCAPCD, THCAPCD, and TOCAPCD and incorporated them into the federally-approved SIP pursuant to section 110(k)(3) of the CAA.

On September 22, 1972 EPA approved KCAPCD Rule 416, Open Burning, into the SIP, and on September 22, 1972 and on March 22, 1978, EPA approved parts of KCAPCD Rule 417, Exceptions, into the SIP. Submitted KCAPCD Rule 416, Open Burning, combines and replaces these two SIP-approved rules and strengthens the rule by adding requirements for an extensive burn plan and a modeling study to limit health risk for open burning/open detonation activities. Submitted Rule 416 regulates PM–10 emissions from open burning activities other than agricultural burning. An earlier submittal of Rule 417, Exceptions (to Rule 416), on which no action was taken, was amended on August 22, 1989, and submitted to EPA on September 14, 1992. While EPA can only act on the most recently submitted version, EPA reviewed relevant materials associated with this superseded earlier version.

On July 6, 1982, EPA approved KCAPCD Rule 417.1, Agricultural Burning, into the SIP. Submitted KCAPCD Rule 417, Agricultural Burning, replaces the SIP-approved rule. Submitted Rule 417 provides for the burning of Tumbleweeds and Star Thistle according to present policy. A section on rice straw burning, not applicable to the desert region, is deleted. Rule 417 is at least as stringent as the SIP-approved rule. There are no superseded submittals of Rule 417 on which EPA has not acted.

On various dates, EPA approved into the SIP versions of submitted NSAQMD Rules 302 to 312 from the three individual counties comprising the NSAQMD. Nevada County Rules 301 to 303 and 316 to 318 were approved on June 14, 1978 and Rules 320 and 321 were approved on September 14, 1978. Plumas County Rules 301 to 303, 306 to 310, and 312 were approved on April 23, 1982. Sierra County Rules 301 and 302, 306 to 310, and 312 were approved on April 23, 1982. Submitted NSAQMD Rules 302 to 312, replace these previous SIP-approved rules and include the following significant changes:

• Burning activities, that were previously allowed on No-Burn Days, are now prohibited on No-Burn Days and include: Abatement of fire hazards, instruction of employees in fire-fighting, agricultural waste burning above 3,000 feet elevation, and residential maintenance burning.

• Burning activities that are now allowed on No-Burn Days, include: Cooking for humans and burning empty pesticide sacks in the field.

On balance, the rules are at least as stringent with respect to activities allowed on No-Burn Days. There are no superseded submittals of NSAQMD open burning rules on which EPA has not acted.

On October 23, 1989, EPA approved into the SIP a version of Rule 4.3, Non-Agricultural Burning. Submitted SCAPCD Rule 4.3, Non-Agricultural Burning, replaces the SIP-approved version of the rule. The rule is strengthened by requiring that the allowance to burn on a No-Burn Day for cooking of food and for recreational purposes be carried out only with ''approved combustibles''. There are no superseded submittals of SCAPCD open burning rules on which EPA has not acted.

On various dates, EPA approved into the SIP versions of submitted SJVUAPCD Rule 4302 from the eight individual counties comprising the SJVUAPCD as follows: Fresno County Rule 417, approved on August 22, 1977; Kern County Rule 418, approved on September 22, 1972; Kings County Rule 418, approved on August 4, 1978; Madera County Rule 423, approved on November 18, 1993; Merced County Rule 417, approved on September 22, 1972; San Joaquin County Rule 417, approved on August 22, 1977; Stanislaus County Rule 417, approved on September 22, 1972; and Tulare County Rule 418, approved on September 22, 1972. The submitted SJVUAPCD Rule 4302 replaces all of these previous SIP-approved rules. Rule 4302 is equally as stringent as the rules of the eight counties and equally as stringent as the rules of six other California air pollution control districts. Rule 4302 is determined to meet the requirements of RACM. There are no superseded submittals of SJVUAPCD incinerator burning rules on which EPA has not acted.

On various dates, EPA approved into the SIP versions of submitted SJVUAPCD Rule 4303 from the eight individual counties comprising the SJVUAPCD as follows: Fresno County Rule 420, approved on September 22, 1972; Kern County Rule 421, approved on September 22, 1972; Kings County Rule 421, approved on August 4, 1978; Madera County Rule 425, approved on April 16, 1991; Merced County Rule 420, approved on September 22, 1972; San Joaquin County Rule 420, approved on August 22, 1977; Stanislaus County Rule 420, approved on September 22, 1972; and Tulare County Rule 421, approved on September 21, 1977. The submitted SJVUAPCD Rule 4303

replaces these previous SIP-approved rules. Rule 4303 is equally as stringent as the rules of the eight counties and equally as stringent as the rules of six other California air pollution control districts. Rule 4303 is determined to meet the requirements of RACM. There are no superseded submittals of SJVUAPCD orchard heater rules on which EPA has not acted.

On April 17, 1989, EPA approved into the SIP a version of THCAPCD Rule 3.12, Wildland Vegetation Management Burning. Submitted THCAPCD Rule 3.12, Wildland Vegetation Management Burning, replaces the SIP-approved rule. The rule is strengthened by requiring that vegetation be in a condition to facilitate combustion and minimize smoke emission. There are no superseded submittals of THCAPCD open burning rules on which EPA has not acted.

On May 27, 1982, EPA approved into the SIP Rules 301 to 319. On November 22, 1988, the TOCAPCD replaced or deleted the SIP-approved Rules 301 to 319. Submitted TOCAPCD Rules 301 to 310, replace these rules. The rules are strengthened by the following changes:

- Requirements for providing 48-hour and 72-hour burn advisories are added.
- Requirements for regulating forest management burning, range improvement burning, and wildland vegetation management burning are added.
- The allowance to burn on No-Burn Days for agricultural waste above 3,000 feet elevation and for agricultural burning above 6,000 feet elevation are eliminated.

There are no superseded submittals of TOCAPCD open burning rules on which EPA has not acted. EPA is not acting on TOCAPCD Rule 301, Compliance, submitted on March 26, 1990, because it is not appropriate for the SIP.

EPA has evaluated the submitted rules and has determined that, except for TOCAPCD Rule 301, they are consistent with the CAA, EPA regulations, and EPA policy. Therefore, the following rules are being approved under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and part D:

- KCAPCD Rule 416, Open Burning (submitted on October 18, 1996).
- KCAPCD Rule 417, Agricultural Burning (submitted on October 18, 1996).
- NSAQMD Rules 302 to 312 (submitted on October 25, 1991):
- NSAQMD Rule 302, Prohibited Open Burning.
- NSAQMD Rule 303, Allowed Open Burning.
- NSAQMD Rule 304, Agricultural Burning.
- NSAQMD Rule 305, Range Improvement Burning.
- NSAQMD Rule 306, Forest Management Burning.
- NSAQMD Rule 307, Wildlands Vegetation Management Burning.
- NSAQMD Rule 308, Land Development Clearing.
- NSAQMD Rule 309, Ditch, Road and Right-of-Way Maintenance.
- NSAQMD Rule 310, Hazard Reduction.
- NSAQMD Rule 311, Residential Maintenance.
- NSAQMD Rule 312, Burning Permits.
- SJVUAPCD Rule 4302, Incinerator Burning (submitted on May 24, 1994).
- SJVUAPCD Rule 4303, Orchard Heaters (submitted on May 24, 1994).
- SKCAPCD Rule 4.3, Non-Agricultural Burning (submitted on March 26, 1990).
- THCAPCD Rule 3.12, Wildland Vegetation Management Burning (submitted on May 13, 1991).

TOCAPCD Rules 302 to 310 (submitted on March 26, 1990):

- TOCAPCD Rule 302, Burning Requirements.
- TOCAPCD Rule 303, Burn or No-Burn Day.
- TOCAPCD Rule 304, Burning Management Requirements.
- TOCAPCD Rule 305, Minimum Drying Times.
- TOCAPCD Rule 306, Agricultural Burning.
- TOCAPCD Rule 307, Wildland Vegetation Management.
- TOCAPCD Rule 308, Forest Management.
- TOCAPCD Rule 309, Range Improvement.
- TOCAPCD Rule 310, Miscellaneous Burning.

EPA is approving the replacement or deletion of the cited SIP-approved rules. A more detailed evaluation can be found in EPA's evaluation reports for the submitted, deleted, or replaced rules.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should relevant adverse comments be filed. This rule will be effective October 18, 1999 without further notice unless the Agency receives relevant adverse comments by September 20, 1999.

If the EPA receives such comments, then EPA will publish a timely withdrawal informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on this rule. Any parties interested in commenting on this rule should do so at this time. If no such comments are received, the public is advised that this rule will be effective on October 18, 1999 and no further action will be taken on the proposed rule.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, Regulatory Planning and Review.

B. Executive Order 12875

Under Executive Order 12875, Enhancing the Intergovernmental Partnership, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an

environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because 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 create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of 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).

F. 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 annual 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 annual 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.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 the **Federal Register**. This rule is not a ''major'' rule as defined by 5 U.S.C. 804(2).

H. 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 18, 1999. 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, Particulate matter, Reporting and recordkeeping requirements.

Dated: July 30, 1999.

David P. Howekamp,

Acting Regional Administrator, Region IX.

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 *et seq.*

Subpart F—California

2. Section 52.220 is amended by adding paragraphs (c)(179)(i)(E)(*3*) and (G)(*2*), (c)(184) introductory text, (i)(D) introductory text and (F)(*2*), (c)(186)(i)(F), (c)(197)(i)(C)(*3*), and (c)(241)(i)(D) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(179) * * *

(i) * * *

(E) * * *

(*3*) Rule 4.3, adopted on January 24, 1989.

(G) * * *

(*2*) Rules 302 to 310, adopted on November 22, 1988.

* * * * *

(184) New and amended regulations for the following APCDs were submitted

on May 13, 1991, by the Governor's designee.

(i) * * *

(D) San Diego County Air Pollution Control District.

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(F) * * *

(*2*) Rule 3.12, adopted on April 25, 1989.

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(186) * * *

(i) * * *

(F) Northern Sierra Air Pollution Control District.

(*1*) Rules 302 to 312, adopted on November 10, 1988.

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(197) * * *

(i) * * *

(C) * * *

(*3*) Rules 4302 and 4303, adopted on May 21, 1992 and amended on December 16, 1993.

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(241) * * *

(i) * * *

(D) Kern County Air Pollution Control District.

(*1*) Rules 416 and 417, adopted on April 18, 1972 and amended on July 11, 1996.

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[FR Doc. 99–21164 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 126–163a; FRL–6419–9]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision; South Coast Air Quality Management District; Ventura County Air Pollution Control District; Mojave Desert Air Quality Management 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 rules from the South Coast Air Quality Management District (SCAQMD), Ventura County Air Pollution Control District (VCAPCD), and Mojave Desert Air Quality Management District (MDAQMD). This approval action will incorporate two rules into the federally approved SIP and remove two rules from the SIP. The intended effect of approving these rules is to regulate emissions of volatile organic compounds (VOCs) in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). The two rules control VOC emissions from storage tank cleaning and degassing operations and from components at crude oil and natural gas production and processing facilities. The two rules to be removed control VOC emissions from pumps, compressors, and relief valves. Thus, EPA is finalizing the approval of these revisions of 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 rule is effective on October 18, 1999 without further notice, unless EPA receives adverse comments by September 20, 1999. If EPA receives such comment, it will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Written comments must be submitted to Andrew Steckel at the Region IX office listed below. Copies of the rules and EPA's evaluation report for each rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rules are available for inspection at the following locations:

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

Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, SW, Washington, DC 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812

South Coast Air Quality Management District, 21865 E. Copley Drive, Diamond Bar, CA 91765–4182.

Ventura County Air Pollution Control District, 702 County Square Drive, Ventura, CA 93003.

Mojave Desert Air Quality Management District, 15428 Civic Drive, Suite 200, Victorville, CA 92392–2383.

FOR FURTHER INFORMATION CONTACT: Max Fantillo, Rulemaking Office, AIR–4, Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1183.

SUPPLEMENTARY INFORMATION:

I. Applicability

The rules being approved into the California SIP include: SCAQMD's Rule 1149, Storage Tank Cleaning and Degassing and VCAPCD's Rule 74.10, Components at Crude Oil and Natural Gas Production and Processing Facilities. The rules being removed from the SIP are MDAQMD's Rule 466, Pumps and Compressors and Rule 467, Safety Pressure Relief Valves. These rules were submitted by the California Air Resources Board (CARB) to EPA on October 13, 1995 (Rule 1149), June 23, 1998 (Rule 74.10), and November 30, 1994 (Rules 466 and 467).

II. Background

On March 3, 1978, EPA promulgated a list of ozone nonattainment areas under the provisions of the Clean Air Act, as amended in 1977 (1977 Act or pre-amended Act), that included the Los Angeles-South Coast Air Basin, the Ventura County area, and the South Desert Air Basin managed by MDAQMD. 43 FR 8964, 40 CFR 81.305. On May 26, 1988, EPA notified the Governor of California, pursuant to section 110(a)(2)(H) of the 1977 Act, that the above districts' portions of the California SIP were inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP–Call). On November 15, 1990, the Clean Air Act Amendments of 1990 were enacted. Public Law 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q. In amended section 182(a)(2)(A) of the CAA, Congress statutorily adopted the requirement that nonattainment areas fix their deficient reasonably available control technology (RACT) rules for ozone and established a deadline of May 15, 1991 for states to submit corrections of those deficiencies.

Section 182(a)(2)(A) applies to areas designated as nonattainment prior to enactment of the amendments and classified as marginal or above as of the date of enactment. It requires such areas to adopt and correct RACT rules pursuant to pre-amended section 172(b) as interpreted in pre-amendment guidance.[1] EPA's SIP-Call used that guidance to indicate the necessary corrections for specific nonattainment areas. The Los Angeles-South Coast Air Basin is classified as extreme; the Ventura County area and the Southeast Desert Air Basin managed by MDAQMD

[1] Among other things, the pre-amendment guidance consists of those portions of the proposed Post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to Appendix D of November 24, 1987 **Federal Register** document'' (Blue Book) (notice of availability was published in the **Federal Register** on May 25, 1988); and the existing control technique guidelines (CTGs).

are classified as severe;[2] therefore, these areas were subject to the RACT fix-up requirement and the May 15, 1991 deadline.

The State of California submitted many RACT rules for incorporation into its SIP on November 30, 1994, October 13, 1995, and June 23, 1998, including the rules being acted on in this document. This document addresses EPA's direct-final action for SCAQMD'S Rule 1149, Storage Tank Cleaning and Degassing, and VCAPCD's Rule 74.10, Components at Crude Oil and Natural Gas Production and Processing Facilities. SCAQMD adopted Rule 1149 on July 14, 1995 and VCAPCD amended Rule 74.10 on March 10, 1998. These submitted rules were found to be complete on November 28, 1995 and August 25, 1998 respectively pursuant to EPA's completeness criteria that are set forth in 40 CFR part 51, appendix V[3] and are being finalized for approval into the SIP. This document also addresses the State of California's request that MDAQMD's Rule 466, Pumps and Compressors, and Rule 467, Safety Pressure Relief Valves, be removed from the SIP.

Rule 1149 controls VOC emissions from the cleaning and degassing of stationary tanks, reservoirs, or other containers; Rule 74.10 sets requirements for controls fugitive VOC emissions from crude oil and natural gas production and processing facilities; rescinded Rules 466 and 467 control VOC emissions from pumps, compressors, and pressure relief valves used in oil and gas production and processing facilities. VOCs contribute to the production of ground level ozone and smog. These rules were originally adopted as part of SCAQMD's, VCAPCD's, and MDAQMD's effort to achieve the National Ambient Air Quality Standard (NAAQS) for ozone and in response to EPA's SIP-Call and the section 182(a)(2)(A) CAA requirement. The following is EPA's evaluation and final action for these rules.

III. EPA Evaluation and Action

In determining the approvability of a VOC rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and part D of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). The EPA interpretation of these requirements, which forms the basis for today's action, appears in the various EPA policy guidance documents listed in footnote 1. Among those provisions is the requirement that a VOC rule must, at a minimum, provide for the implementation of RACT for stationary sources of VOC emissions. This requirement was carried forth from the pre-amended Act.

For the purpose of assisting state and local agencies in developing RACT rules, EPA prepared a series of Control Technique Guideline (CTG) documents. The CTGs are based on the underlying requirements of the Act and specify the presumptive norms for what is RACT for specific source categories. Under the CAA, Congress ratified EPA's use of these documents, as well as other Agency policy, for requiring States to ''fix-up'' their RACT rules. See section 182(a)(2)(A). There is no CTG document directly applicable to Rule 1149. However, CTG documents used as guidance in evaluating Rule 1149 are entitled, ''Control of Volatile Organic Emissions from Storage of Petroleum Liquids in Fixed-Roof Tanks,'' EPA–450/2–77–036 and ''Control of Volatile Organic Emissions from Petroleum Liquid Storage in External Floating Roof Tanks,'' EPA–450/2–78–047. The CTG applicable to Rule 74.10 is entitled, ''Control of Volatile Organic Compound Equipment Leaks from Natural Gas/Gasoline Processing Plants,'' EPA–450/3–83–007. Further interpretations of EPA policy are found in the Blue Book, referred to in footnote 1. In general, these guidance documents have been set forth to ensure that VOC rules are fully enforceable and strengthen or maintain the SIP.

SCAQMD Rule 1149 is a new rule which controls VOC emissions from the degassing of petroleum storage tanks, reservoirs, or other containers. Above-ground containers and underground tanks are subject to this rule depending upon their capacity and the vapor pressure of the stored organic liquid. The rule requires degassing emissions to be controlled by at least 90%, using several methods, including, liquid balancing, negative pressure displacement with subsequent incineration, or refrigeration. Monitoring of refrigeration and carbon adsorption is required, along with records of monitoring results, vapor pressures, and degassing operations.

On August 17, 1994, EPA approved into the SIP a version of Rule 74.10, Components at Crude Oil and Natural Gas Production and Processing Facilities, that had been adopted by VCAPCD on June 16, 1992. Revisions to this rule were subsequently adopted on March 10, 1998 and submitted to EPA. VCAPCD's submitted Rule 74.10, Components at Crude Oil and Natural Gas Production and Processing Facilities include the following significant changes from the current SIP:

- Expanded the applicability by including pipeline transfer stations.
- Added new requirements for inspection, inspection frequency, and monitoring, and more stringent retrofit and/or replacement requirements for critical components.
- Added an option to change from quarterly to annual inspection.
- Tightened deadlines for both the initial and final repair of leaks.
- Added exemptions for certain components meeting certain conditions and recordkeeping requirements for leaks.
- Updated the test methods for measurement of ROC concentrations.
- Added violation requirements for liquid leaks.
- Added new definitions and revised others for clarity.

MDAQMD's Rule 466, Pumps and Compressors and Rule 467, Safety Pressure Relief Valves were submitted to be removed from the SIP. These rules were adopted to control volatile organic compounds emissions from pumps, compressors, and pressure relief valves within the Southeast Desert Air Basin managed by MDAQMD. Rule 1102 was adopted to replace Rules 466 and 467. Rule 1102 was approved into the SIP on September 27, 1995 (60 FR 49772). This rule covers the scope and emission limitations that Rules 466 and 467 currently have in the SIP. Consequently, MDAQMD is rescinding Rules 466 and 467 because they no longer apply and are extraneous. Further, no limits are relaxed or emission increase by this action. The removal of Rules 466 and 467 from the SIP are consistent with EPA's policy requirements and remove extraneous rules that serve no purpose.

EPA has evaluated the submitted rules and has determined that they are consistent with the CAA, EPA regulations, and EPA policy. Therefore, SCAQMD's Rule 1149, Storage Tank Cleaning and Degassing, and VCAPCD's Rule 74.10, Components at Crude Oil and Natural Gas Production and Processing Facilities are being approved under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and part D. Furthermore, EPA is removing MDAQMD's Rules 466 and

[2] The Los Angeles-South Coast Air Basin, Ventura County area, and the Southeast Desert Air Basin managed by MDAQMD retained their designations of nonattainment and were classified by operation of law pursuant to sections 107(d) and 181(a) upon the date of enactment of the CAA. See 56 FR 56694 (November 6, 1991).

[3] EPA adopted the completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to section 110(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

467 consistent with the requirements of sections 110(l) and 193.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective October 18, 1999 without further notice unless the Agency receives adverse comments by September 20, 1999.

If the EPA receives such comments, then EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting on this rule should do so at this time. If no such comments are received, the public is advised that this rule is effective on October 18, 1999 and no further action will be taken on the proposed rule.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, Regulatory Planning and Review.

B. Executive Order 12875

Under Executive Order 12875, Enhancing the Intergovernmental Partnership, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This rule is not subject to E.O. 13045 because it is does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because 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 create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of 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).

F. 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 annual 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 annual 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.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 the **Federal Register**. This rule is not a ''major'' rule as defined by 5 U.S.C. 804(2).

H. 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 18, 1999. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 30, 1999.

David P. Howekamp,

Acting Regional Administrator, Region IX.

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 *et seq.*

Subpart F—California

2. Section 52.220 is amended by adding paragraphs (c)(39)(ii)(G), (c)(225)(i)(A)(4) and (c)(256)(i)(F)(1) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(39) * * *

(ii) * * *

(G) Previously approved on October 8, 1978 and now deleted without replacement Rules 466 and 467.

* * * * *

(225) * * *

(i) * * *

(A) * * *

(4) Rule 1149, adopted on December 4, 1987 and amended on July 14, 1995.

* * * * *

(256) * * *

(i) * * *

(F) Ventura County Air Pollution Control District.

(1) Rule 74.10, adopted on September 29, 1981 and amended on March 10, 1998.

* * * * *

[FR Doc. 99–21162 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 172–0157a; FRL–6420–3]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision: Bay Area Air Quality Management District, Kern County Air Pollution Control District, Monterey Bay Unified Air Pollution Control District, South Coast Air Quality Management 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 (SIP). The revisions concern rules from the following districts: Bay Area Air Quality Management District—Rule 8–26, Magnet Wire Coating Operations; Kern County Air Pollution Control District—Rule 410.4, Surface Coating of Metal Parts and Products; Monterey Bay Unified Air Pollution Control District—Rule 434, Coating of Metal Parts and Products; and, South Coast Air Quality Management District—Rule 1107, Coating of Metal Parts and Products. This approval action will incorporate these rules within the federally approved SIP. The intended effect of approving these rules is to regulate emissions of volatile organic compounds (VOCs) according to the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). The revised rules control VOC emissions from the surface coating of magnet wire and miscellaneous metal parts and products. 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 rule is effective on October 18, 1999 without further notice, unless EPA receives adverse comments by September 20, 1999. If EPA receives such comment, it will publish a timely withdrawal notice in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Written comments must be submitted to Andrew Steckel at the Region IX office listed below. Copies of the rule revisions and EPA's evaluation report for each rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule revisions are available for inspection at the following locations:

Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105 Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, SW, Washington, D.C. 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812

Bay Area Air Quality Management District, 939 Ellis Street, San Francisco, CA 94109

Kern County Air Pollution Control District, 2700 M Street, Suite 302, Bakersfield, CA 93301

Monterey Bay Unified Air Pollution Control District, 24580 Silver Cloud Court, Monterey, CA 93940

South Coast Air Quality Management District, 218 East Copley Drive, Diamond Bar, CA 91765

FOR FURTHER INFORMATION CONTACT: Jerald S. Wamsley, Rulemaking Office, AIR–4, Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1226.

SUPPLEMENTARY INFORMATION:

I. Applicability

EPA is approving the following rules into the California SIP:

—Bay Area Air Quality Management District (BAAQMD)—Rule 8–26, Magnet Wire Coating Operations;

—Kern County Air Pollution Control District (KCAPCD)—Rule 410.4, Surface Coating of Metal Parts and Products;

—Monterey Bay Unified Air Pollution Control District (MBUAPCD)—Rule 434, Coating of Metal Parts and Products; and,

—South Coast Air Quality Management District (SCAQMD)—Rule 1107, Coating of Metal Parts and Products.

These rules were submitted by the California Air Resources to EPA on July 23, 1996 (BAAQMD Rule 8–26), May 10, 1996 (KCAPCD 410.4), March 3, 1997 (MBUAPCD Rule 434), February 16, 1999 (SCAQMD Rule 1107).

II. Background

On March 3, 1978, EPA promulgated a list of ozone nonattainment areas under the provisions of the Clean Air Act, as amended in 1977 (1977 Act or pre-amended Act), that included the San Francisco Bay, the Southeast Desert Modified Air Quality Management Area, Monterey Bay, and the South Coast ozone nonattainment areas (see 43 FR 8964, 40 CFR 81.305.) On May 26, 1988, EPA notified the Governor of California, pursuant to section 110(a)(2)(H) of the 1977 Act, that the portions of the California SIP represented by these areas were inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). On November 15, 1990, the Clean Air Act Amendments of 1990 were enacted. Public Law 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q. In amended section 182(a)(2)(A) of the CAA, Congress statutorily adopted the requirement that nonattainment areas fix their deficient reasonably available control technology (RACT) rules for ozone and established a deadline of May 15, 1991 for states to submit corrections of those deficiencies.

Section 182(a)(2)(A) applies to areas designated as nonattainment prior to enactment of the amendments and classified as marginal or above as of the date of enactment. It requires such areas to adopt and correct RACT rules pursuant to pre-amended section 172 (b) as interpreted in pre-amendment guidance.[1] EPA's SIP-Call used that guidance to indicate the necessary corrections for specific nonattainment areas. The nonattainment areas subject to this rulemaking were classified as follows: Bay Area—moderate; Monterey Bay—moderate; and South Coast—extreme.[2] Therefore, these areas are subject to the RACT fix-up requirement and the May 15, 1991 deadline.

The Bay Area ozone nonattainment area was redesignated to attainment on May 22, 1995 (see 60 FR 27028). Subsequently, based on violations of the ozone NAAQS, EPA redesignated the San Francisco Bay Area to nonattainment without classification on July 10, 1998 (see 63 FR 37258). The Monterey Bay Area was redesignated as an attainment area for the ozone standard on January 17, 1997 (see 62 FR 2597).

The Southeast Desert Air Basin portion of Kern County was not a pre-amendment nonattainment area, so it was not designated and classified upon enactment of the amended Act. Consequently, KCAPCD is not subject to the section 182(a)(2)(A) RACT fix-up requirement. The KCAPCD is subject to the requirements of EPA's SIP-Call, because the SIP-Call included all of Kern County.

The State of California submitted many revised RACT rules for incorporation into its SIP. CARB submitted the rules subject to this rulemaking action to EPA on July 23, 1996 (BAAQMD Rule 8–26), May 10, 1996 (KCAPCD Rule 410.4), March 3, 1997 (MBUAPCD Rule 434), February 16, 1999 (SCAQMD Rule 1107). This document addresses EPA's direct-final action for Bay Area Air Quality Management District—Rule 8–26, Magnet Wire Coating Operations adopted and revised December 20, 1995; Kern County Air Pollution Control District—Rule 410.4, Surface Coating of Metal Parts and Products adopted and revised March 7, 1996; Monterey Bay Unified Air Pollution Control District—Rule 434, Coating of Metal Parts and Products adopted and revised December 18, 1996; and, South Coast Air Quality Management District—Rule 1107, Coating of Metal Parts and Products adopted and revised on August 18, 1998.

These submitted rules were found to be complete pursuant to EPA's completeness criteria set forth in 40 CFR part 51, appendix V.[3] EPA found the subject rules complete on the following dates: October 30, 1996 (BAAQMD Rule 8–26), July 19, 1996 (KCAPCD Rule 410.4), August 12, 1997 (MBUAPCD Rule 434), April 23, 1999 (SCAQMD Rule 1107).

EPA is taking direct final action to approve these revisions to the California SIP.

These rules are prohibitory rules governing the use and application of coating compounds containing photochemically reactive volatile organic compounds (VOCs) in their respective industries. VOCs contribute to the production of ground level ozone and smog. These rules were adopted originally as part of each air district's effort to achieve the National Ambient Air Quality Standard (NAAQS) for ozone and in response to EPA's SIP-Call and the section 182(a)(2)(A) CAA requirement. EPA's evaluation and final action for these rules follows in the next section.

III. EPA Evaluation and Action

When deciding whether or not to approve a VOC rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and part D of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). The EPA interpretation of these requirements, which forms the basis for today's action, appears in the various EPA policy guidance documents listed in footnote one. Among those provisions is the requirement that a VOC rule must, at a minimum, provide for the implementation of RACT for stationary sources of VOC emissions. This requirement was carried forth from the pre-amended Act.

For the purpose of assisting state and local agencies in developing RACT rules, EPA prepared a series of Control Technique Guideline (CTG) documents. The CTGs are based on the underlying requirements of the Act and specify the presumptive norms for what is RACT for specific source categories. Under the CAA, Congress ratified EPA's use of these documents, as well as other

[1] Among other things, the pre-amendment guidance consists of those portions of the proposed Post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to Appendix D of November 24, 1987 **Federal Register** Document'' (Blue Book) (notice of availability was published in the **Federal Register** on May 25, 1988); and the existing control technique guidelines (CTGs).

[2] Bay Area, Monterey Bay, and South Coast nonattainment areas retained their designation of nonattainment and were classified by operation of law pursuant to sections 107(d) and 181(a) upon the date of enactment of the CAA. At the same time the Southeast Desert Air Basin Portion of Kern County was designated nonattainment. See 56 FR 56694 (November 6, 1991).

[3] EPA adopted the completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to section 110(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

Agency policy, for requiring States to ''fix-up'' their RACT rules. See section 182(a)(2)(A). The CTGs applicable to these rules are entitled as follows:

—''Control of Volatile Organic Emissions from Existing Stationary Sources, Volume IV: Surface Coating for the Insulation of Magnet Wire,'' USEPA, December 1977, EPA–450/2–77–033; and,

—''Control of Volatile Organic Emissions from Existing Stationary Sources Volume VI: Surface Coating of Miscellaneous Metal Parts and Products,'' USEPA, June 1978, EPA–450/2–78–015.

Further interpretations of EPA policy are found in the Blue Book, referred to in footnote one. In general, these guidance documents have been set forth to ensure that VOC rules are fully enforceable and strengthen or maintain the SIP.

In the past, EPA approved into the SIP prior versions of each subject rule. On July 8, 1982, EPA approved into the SIP a prior version of BAAQMD Rule 8–26 (see 47 FR 29668.) This version of Rule 8–26 was adopted by the BAAQMD Governing Board on May 7, 1980. Prior to the December 20, 1995 revisions to Rule 8–26, BAAQMD revised Rule 8–26 on March 17, 1982. Consequently, this review of Rule 8–26 addresses this past, as well as, the recent December 20, 1995 revision of the rule.

The BAAQMD's submitted Rule 8–26, Magnet Wire Coating Operations, included the following significant change from the current SIP rule.

—Rule 8–26's definition of volatile organic compounds was revised.

The March 17, 1982 amendments to Rule 8–26 added two test methods at 8–26–601, Analysis of Samples and 8–26–602, Determination of Emissions.

The definition change and test method additions within submitted Rule 8–26 do not interfere with reasonable further progress or attainment of the NAAQS. These 1982 and 1995 changes to Rule 8–26 either update or improve the clarity of the rule. Consequently, the changes within submitted BAAQMD Rule 8–26 are consistent with the requirements of section 110(l) of the CAA.

EPA has evaluated the BAAQMD's submitted rule and has determined that it is consistent with the CAA, EPA regulations, and EPA policy. Therefore, BAAQMD Rule 8–26, Magnet Wire Coating Operations is being approved under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and part D.

EPA approved into the SIP a prior version of KCAPCD's Rule 410.4, Surface Coating of Metal Parts and Products, on July 25, 1996 (see 61 FR 38571). The KCAPCD Governing Board adopted this version of Rule 410.4 on April 6, 1995.

KCAPCD's submitted Rule 410.4, Surface Coating of Metal Parts and Products includes the following significant change from the current SIP rule.

—Rule 410.4's definitions for exempt compounds and volatile organic compounds have been removed and the rule now refers to Rule 102—Definitions for these terms.

The definition change within submitted Rule 410.4 does not interfere with reasonable further progress or attainment of the NAAQS. This change updates the rule. Consequently, the change within submitted KCAPCD Rule 410.4 is consistent with the requirements of section 110(l) of the CAA.

EPA has evaluated the KCAPCD's submitted rule and has determined that it is consistent with the CAA, EPA regulations, and EPA policy. Therefore, KCAPCD Rule 410.4—Surface Coating of Metal Parts and Products is being approved under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and part D.

EPA approved a prior version of MBUAPCD's Rule 434, Coating of Metal Parts and Products on February 12, 1996 (see 61 FR 5288). This version of Rule 434 was adopted by the MBUAPCD Governing Board on June 15, 1994. MBUAPCD's submitted Rule 434—Coating of Metal Parts and Products included these significant changes from the current SIP described below.

—Rule 434's definitions for exempt compounds and volatile organic compounds have been removed and the Rule 434 now refers to Rule 101—Definitions for these terms.

—The VOC emissions limit for pretreatment wash primers were increased from 420 grams/litre (g/l) to 780 g/l.

—Recordkeeping requirements were revised to require daily recordkeeping for the use of non-compliant coatings.

—Lastly, the test method for determining pollution control equipment capture efficiency was updated.

The VOC content limits, recordkeeping, and test method revisions within submitted Rule 434 do not interfere with reasonable further progress or attainment of the NAAQS. MBUAPCD stated there are no permitted sources within the district using pretreatment wash primer. As a result, MBUAPCD did not perform a five percent analysis justifying the de minimis effect of raising this emission limit. However, should sources using pretreatment wash primer begin coating operations within MBUAPCD, EPA will require the MBUAPCD to conduct a five percent analysis to demonstrate the continued de minimis emissions effect of the 780 g/l emissions limit.

EPA has evaluated the MBUAPCD's submitted rule and has determined that it is consistent with the CAA, EPA regulations, and EPA policy. Therefore, MBUAPCD Rule 434—Coating of Metal Parts and Products is being approved under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and part D.

On July 14, 1995, EPA approved into the SIP a prior version of SCAQMD—Rule 1107, Coating of Metal Parts and Products (see 60 FR 36227). The SCAQMD Governing Board adopted this version of Rule 1107 on May 12, 1995. Prior to the August 14, 1998 revisions to Rule 1107, SCAQMD revised a set of rules including Rule 1107. The SCAQMD Governing Board adopted these revisions on March 8, 1996 and the CARB submitted them to EPA on July 23, 1996. EPA has not acted on this set of revisions. However, because the March 8, 1996 revisions to Rule 1107 are incorporated within the later August 14, 1998 revisions and adoption, EPA's review of Rule 1107 addresses both this past as well as the most recent revisions of the rule.

The significant changes from the current SIP within SCAQMD's August 14, 1998 submittal of Rule 1107 are described below.

—The VOC content limit is lowered for general category single-component air-dried coating from 340 gram/liter (gr/l) to 275 gr/l (2.3 lb VOC/gal), less water and exempt compounds beginning March 1, 1999.

—A small use exemption for facilities using less than one gallon of coating per day is removed after March 1, 1999.

—A small use exemption for facilities using less than 55 gallons per rolling 12 month period is removed after March 1, 1999. However, this exemption is retained for sources using essential public service coatings for repair and maintenance procedures.

—An exemption is allowed for electric insulating and thermally conductive coatings.

The March 8, 1996 amendments to Rule 1107 removed the definition of exempt compounds which was placed for ease of revision within Rule 102—Definition of Terms. Also, because

changes to California law prohibited air districts from regulating aerosol applications and placed this authority with the CARB, the SCAQMD exempted aerosol coating products from Rule 1107. Now, CARB regulates aerosol coatings through their consumer products regulations.

The modified VOC content limits and exemption levels within submitted Rule 1107 do not interfere with reasonable further progress or attainment of the NAAQS. The VOC content limits have been strengthened and the exemption criteria are narrowed. The changes to Rule 1107 increase VOC emission reductions compared to the 1995 version of the rule within the SIP. SCAQMD calculated that VOC emissions are reduced by an additional 1.01 tons/per day or 368.7 tons per year. For these reasons, the changes within submitted Rule 1107 are consistent with the requirements of section 110(l) of the CAA.

EPA has evaluated the SCAQMD's submitted rule and has determined it is consistent with the CAA, EPA regulations, and EPA policy. Therefore, SCAQMD—Rule 1107, Coating of Metal Parts and Products, is being approved under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and part D.

Nothing in this action should be construed as permitting, 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.

EPA is publishing this rulemaking action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective October 18, 1999 without further notice unless the Agency receives adverse comments by September 20, 1999.

If the EPA receives such comments, then EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting on this rule should do so at this time. If no such comments are received, the public is advised that this rule is effective on October 18, 1999 and no further action will be taken on the proposed rule.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, Regulatory Planning and Review.

B. Executive Order 12875

Under Executive Order 12875, Enhancing the Intergovernmental Partnership, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because 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 create any new requirements, I certify that this

action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of 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).

F. 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 annual 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 annual 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.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 the **Federal Register**. This rule is not a ''major'' rule as defined by 5 U.S.C. 804(2).

H. 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 18, 1999. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 30, 1999.

David P. Howekamp,

Acting Regional Administrator, Region IX.

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 *et seq.*

Subpart F—California

2. Section 52.220 is amended by adding paragraphs (c)(231)(i)(B)(*6*), (c)(239)(i)(E)(*5*), (c)(244)(i)(A)(*4*), and (c)(262)(i)(C) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(231) * * *

(i) * * *

(B) * * *

(*6*) Rule 410.4, adopted on June 26, 1979 and amended on March 7, 1996.

* * * * *

(239) * * *

(i) * * *

(E) * * *

(*5*) Rule 8–26, adopted on May 7, 1980 and amended on December 20, 1995.

* * * * *

(244) * * *

(i) * * *

(A) * * *

(*4*) Rule 434, adopted on December 18, 1996.

* * * * *

(262) * * *

(i) * * *

(C) South Coast Air Quality Management District.

(*1*) Rule 1107, adopted on June 1, 1979 and amended on August 14, 1998.

* * * * *

[FR Doc. 99–21160 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD077a–3034; FRL–6419–1]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Control of VOC Emissions From Reinforced Plastics Manufacturing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a revision to the Maryland State Implementation Plan (SIP). The revision establishes and requires reasonably available control technology (RACT) for volatile organic compound (VOC) emissions from reinforced plastic manufacturing. EPA is approving the addition of a new subsection to COMAR 26.11.19 ''Volatile Organic Compounds from Specific Processes Control'' as a revision to the Maryland SIP in accordance with the requirements to the Clean Air Act.

DATES: This rule is effective October 18, 1999 without further notice, unless EPA receives adverse written comment by September 20, 1999. If EPA receive such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments should be mailed to Walter Wilkie, Acting Chief, Technical Assessment Branch, Mailcode 3AP22, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460; Maryland Department of the Environment, 2500 Broening Highway, Baltimore Maryland 21224.

FOR FURTHER INFORMATION CONTACT: Walter Wilkie at (215) 814–2150, or by e-mail at wilkie.walter@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On August 28, 1998, the State of Maryland submitted a formal revision to its State Implementation Plan (SIP). The SIP revision consists of amendments to COMAR 26.11.19, ''Volatile Organic Compounds from Specific Processes.'' The purpose of the amendments to COMAR 26.11.19 is to establish VOC emission control requirements on sources that manufacture reinforced plastics. The revision was submitted to satisfy requirements of section 182 and 184 of the Clean Air Act to implement reasonably available control technology (RACT) on major sources of VOC.

II. Summary of the SIP Revision

This SIP revision includes the addition of new subsection .26 ''Control of Volatile Organic Compound Emissions from Reinforced Plastic Manufacturing'' to COMAR 26.11.19 ''Volatile Organic Compound from Specific Processes.'' COMAR 26.11.19.26 establishes RACT requirements for VOC emissions from reinforced plastic manufacturing operations. COMAR 26.11.19.26 applies statewide. The regulation applies to reinforced plastic manufacturing operations at premises where the total actual VOC emissions from all reinforced plastics manufacturing including tooling, touch up and repair is 20 or more pounds per day. The regulation requires the use of low styrene resins. A low styrene resin is defined as a polyester resin with a monomer content of 35 percent or less by weight. The regulation provides an exemption for users of specialty resins. The user of a specialty resin is prohibited from using speciality resins with a styrene content exceeding 50 percent by weight. The higher styrene content is allowed for specialty resins used in special applications involving more stringent specifications such as: higher tensile strength, corrosion resistance, gel coats and fire retardation. The regulation also requires that subject sources with emissions of 100 pounds per day or more use an improved application method such as airless or air assisted spray guns, low pressure nozzles, pressure fed rollers or flow coaters, or some other nonatomized resin application technique.

EPA has determined that the control requirements of COMAR 26.11.19.26 constitute an acceptable level of RACT to control VOCs from reinforced plastics manufacturing . EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the ''Proposed Rules'' section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the Maryland SIP revision should adverse comments be filed. This rule will be effective on October 18, 1999 without further notice unless the Agency receives adverse comments by September 20, 1999. If EPA receives comments, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting should do so at this time.

II. Final Action

EPA is approving the SIP revision to add subsection .26 ''Control of Volatile Organic Compound Emissions from Reinforced Plastics Manufacturing'' to COMAR 26.11.19 submitted by the State of Maryland on August 28, 1998.

III. Administrative Requirements

A. Executive Orders 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from review under E.O. 12866, entitled ''Regulatory Planning and Review.''

B. Executive Order 12875

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If EPA complies by consulting, E.O. requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation. In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

C. Executive Order 13045

E.O. 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), applies to any rule that the EPA determines: (1) Is ''economically significant,'' as defined under E.O. 12866, and (2) the environmental health or safety risk addressed by the rule has a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is not subject to E.O. 13045 because it is not an economically significant regulatory action as defined by E.O. 12866, and it does not address an environmental health or safety risk that would have a disproportionate effect on children.

D. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the

requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because 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 create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, 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).

F. 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 annual 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 annual 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.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

H. 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 18, 1999. 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 approving RACT for the control of VOC emissions from reinforced plastics manufacturing under the Maryland SIP may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Ozone, Reporting and recordkeeping requirements.

Dated: August 2, 1999.

W. Michael McCabe,

Regional Administrator, Region III.

40 CFR part 52 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 *et seq.*

Subpart V—Maryland

2. Section 52.1070 is amended by adding paragraphs (c)(139) to read as follows:

§ 52.1070 Identification of plan.

* * * * *

(c) * * *

(139) Revisions to the Maryland State Implementation Plan, submitted on August 28, 1998, by the Maryland Department of the Environment.

(i) Incorporation by reference.

(A) Letter of August 28, 1998, from the Maryland Department of the Environment transmitting additions to Code of Maryland Administrative Regulations (COMAR) 26.11.19 Volatile Orgranic Compounds from Specific Processes.

(B) Addition of COMAR 26.11.19.26 Control of Volatile Organic Compounds from Reinforced Plastic Manufacturing, effective August 11, 1997.

(ii) Additional Material: Remainder of August 28, 1998, State submittal pertaining to the addition of COMAR 26.11.19.26 Control of Volatile Organic Compounds from Reinforced Plastic Manufacturing to COMAR 26.11.19 Volatile Organic Compounds from Specific Processes.

[FR Doc. 99–21158 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[MO 080–1080a; FRL–6421–6]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Control of Emissions From Hospital/Medical/Infectious Waste Incinerators (HMIWIs); State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving the state of Missouri's section 111(d) plan for controlling emissions from existing HMIWIs. The plan was submitted to fulfill the requirements of sections 111 and 129 of the Clean Air Act (CAA). The state plan establishes emission limits and controls for sources constructed on or before June 20, 1996.

DATES: This direct final rule is effective on October 18, 1999, without further notice, unless EPA receives adverse comment by September 20, 1999. If adverse comment is received, EPA will publish a timely withdrawal of the

direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: All comments should be addressed to: Wayne Kaiser, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

Copies of the state submittal are available at the following addresses for inspection during normal business hours: Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101; and the Environmental Protection Agency, Air and Radiation Docket and Information Center, Air Docket (6102), 401 M Street, SW, Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Wayne Kaiser at (913) 551–7603.

SUPPLEMENTARY INFORMATION: Information regarding this action is presented in the following order:

What are the requirements of section 129 of the CAA?
What is a section 111(d) state plan?
What is Subpart Ce?
What are the requirements for the HMIWI state plan?
What is contained in the Missouri state plan?
What are the approval criteria for the state plan?

What Are the Requirements of Section 129 of the CAA?

Section 129 of the CAA Amendments of 1990 requires EPA to set air emission standards and emission guidelines (EG) under the authority of section 111 of the CAA to reduce pollution from incinerators that burn solid waste. Incinerators that burn medical waste are classified as solid waste incinerators and therefore must be regulated.

What is a Section 111(d) State Plan?

Section 111(d) of the CAA, ''Standards of Performance for New Stationary Sources,'' authorizes EPA to set air emissions standards for certain categories of sources. These standards are called new source performance standards (NSPS). When an NSPS is promulgated for new sources, EPA also publishes an EG applicable to the control of the same pollutant from existing (designated) facilities. States with designated facilities must then develop a state plan to adopt the EG into its body of regulations and submit it to EPA for approval. The state plan is called a 111(d) plan.

What is Subpart Ce?

EPA issued regulations to reduce air pollution from incinerators that are used to burn hospital waste and/or medical/infectious waste. The NSPS at 40 CFR part 60, subpart Ec, and the EG, subpart Ce, were promulgated by EPA on September 15, 1997 (62 FR 48374). These rules apply to new and existing incinerators used by hospitals and health care facilities, as well as to incinerators used by commercial waste disposal companies to burn hospital waste and/or medical/infectious waste. The EG applies to existing HMIWIs that commenced construction on or before June 20, 1996.

The subpart Ce EG is not a direct Federal regulation but is a ''guideline'' for states to use in regulating existing HMIWIs. The EG requires states to submit for EPA approval a section 111(d) state plan containing air emission regulations and compliance schedules for existing HMIWI.

What Are the Requirements for the HMIWI State Plan?

A section 111(d) state plan submittal must meet the requirements of 40 CFR part 60, subpart B, sections 60.23 through 60.26, and subpart Ce. Subpart B addresses public participation, legal authority, emission standards and other emission limitations, compliance schedules, emission inventories, source surveillance, and compliance assurance and enforcement requirements. The technical requirements for existing HMIWI sources are contained in subpart Ce. A state will generally address the HMIWI technical requirements by adopting by reference subpart Ce. The section 111(d) state plan is required to be submitted within one year of the EG promulgation date, i.e., by September 15, 1998.

Prior to submittal to EPA, the state must make available to the public the state plan and provide opportunity for public comment. If a state fails to have an approvable plan in place by September 15, 1999, sources will be subject to a Federal plan on that date.

What Is Contained in the Missouri State Plan

The state of Missouri submitted its section 111(d) state plan to EPA for approval on June 15, 1999. The state adopted the EG requirements into state Rule 10 CSR 10–6.200, ''Hospital, Medical, Infectious Waste Incinerators,'' which was effective July 30, 1999. The section 111(d) state plan contains:

1. A demonstration of the state's legal authority to implement the section 111(d) state plan.
2. State Rule 10 CSR 10–6.200, ''Hospital, Medical, Infectious Waste Incinerators,'' as the enforceable mechanism.
3. An inventory of sources on pages 7 and 8.
4. An emissions inventory in Appendix G.
5. Emission limits, as protective as the EG, that are contained in state Rule 10 CSR 10–6.200.
6. A compliance date of September 1, 2000.
7. Testing, monitoring, and inspection requirements that are contained in Rule 10 CSR 10–6.200.
8. Reporting and recordkeeping requirements for the designated facilities that are contained in Rule 10 CSR 10–6.200.
9. Operator training and qualification requirements that are contained in Rule 10 CSR 10–6.200.
10. Requirements for the development of waste management plans that are contained in Rule 10 CSR 10–6.200.
11. A record of the public notice and hearing requirements that is contained in appendix E.
12. Provisions for progress reports to EPA that are contained in section L.
13. Title V permit application due date requirements that are contained in section M.
14. A final compliance date of September 1, 2000.

What Are the Approval Criteria for the State Plan?

The state plan was reviewed for approval against the following criteria: 40 CFR 60.23 through 60.26, subpart B, ''Adoption and Submittal of State Plans for Designated Facilities,'' and 40 CFR 60.30e through 60.39e, subpart Ce, ''Emission Guidelines and Compliance Times for Hospital/Medical/Infectious Waste Incinerators.'' A detailed discussion of our evaluation of the state plan is included in our technical support document (TSD) located in the official file for this action and available from the EPA contact listed above. The state plan meets all of the applicable approval criteria.

Final Action

Based on the rationale discussed above and in further detail in the TSD associated with this action, we are approving Missouri's June 15, 1999, section 111(d) state plan for the control of HMIWI emissions, except for those facilities located in Indian country. Any facilities located in Indian country will be subject to a Federal plan. In Missouri there are no known HMIWIs in Indian country.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed

rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective October 18, 1999, without further notice unless the Agency receives adverse comments by September 20, 1999.

If EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are received, the public is advised that this rule will be effective on October 18, 1999, and no further action will be taken on the proposed rule.

Administrative Requirements

A. Executive Order (E.O.) 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866, entitled ''Regulatory Planning and Review.''

B. E.O. 12875

Under E.O. 12875, Enhancing the Intergovernmental Partnership, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, E.O. 12875 requires EPA to provide to the OMB a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, a summary of the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create a mandate on state, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

C. E.O. 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it is not an economically significant regulatory action as defined by E.O. 12866, and it does not address an environmental health or safety risk that would have a disproportionate effect on children.

D. E.O. 13084

Under E.O. 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, E.O. 13084 requires EPA to provide to the OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, E.O. 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act (RFA)

Under the RFA, 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.

State plan approvals under section 111 of the CAA do not create any new requirements but simply approve requirements that the state is already imposing. Therefore, because the Federal state plan approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

F. 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 annual costs to state, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual 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.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must

submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the U.S. Comptroller General prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

H. 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 18, 1999. 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 62

Environmental protection, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: August 4, 1999.

William Rice,

Acting Regional Administrator, Region VII.

Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 62—[AMENDED]

1. The authority citation for Part 62 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart AA—Missouri

2. Subpart AA is amended by adding section 62.6358 and an undesignated center heading to read as follows:

Air Emissions From Existing Hospital/Medical/Infectious Waste Incinerators

§ 62.6358 Identification of plan.

(a) Identification of plan. Missouri plan for the control of air emissions from hospital/medical/infectious waste incinerators submitted by the Missouri Department of Natural Resources on June 15, 1999.

(b) Identification of sources. The plan applies to existing hospital/medical/infectious waste incinerators constructed on or before June 20, 1996.

(c) Effective date. The effective date of the plan is October 18, 1999.

[FR Doc. 99–21309 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–6419–5]

National Emission Standards for Hazardous Air Pollutants: Halogenated Solvent Cleaning

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: On December 2, 1994, the EPA issued the ''National Emission Standards for Hazardous Air Pollutants: Halogenated Solvent Cleaning'' (59 FR 61801). Today's action offers compliance options for continuous web cleaning machines, as well as amendments to the national emission standards for hazardous air pollutants (NESHAP) that apply to steam-heated vapor cleaning machines and to cleaning machines used to clean transformers. The EPA is approving these amendments to ensure that all owners or operators of solvent cleaning machines have appropriate and attainable requirements for their cleaning machines.

DATES: This direct final rule will be effective on October 18, 1999 without further notice, unless the EPA receives adverse comments by September 20, 1999. If we receive any adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Written comments should be submitted (in duplicate, if possible) to: Air and Radiation Docket and Information Center (MC–6102), Attention Docket Number A–92–39, Room M–1500, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. The EPA requests that a separate copy of each public comment be sent to the contact person listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: For information concerning the standards and the proposed changes, contact Mr. Paul Almodóvar, Coatings and Consumer Products Group, Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–0283. For information regarding the applicability of this action to a particular entity, contact Ms. Acquanetta Delaney, Manufacturing Branch, Office of Compliance (2223A), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; telephone (202) 564–7061.

SUPPLEMENTARY INFORMATION: The EPA is publishing this rule without prior proposal because we view this as a noncontroversial amendment and do not anticipate adverse comment. The changes to the compliance requirements for continuous web cleaning machines provide the only reasonable method available to those cleaning machines to comply with the maximum achievable control technology (MACT) level of control. The EPA considers these revised requirements to be comparable to the requirements previously promulgated for other cleaning machines. However, in the ''Proposed Rules'' section of today's **Federal Register**, we are publishing a separate document that will serve as the proposal in the event that adverse comments are filed. This rule will be effective on October 18, 1999 without further notice unless we receive any adverse comment by September 20, 1999. If we receive any adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

Regulated Entities

The following entities are potentially regulated by this direct final rule.

Category	SIC codes	Examples of potentially regulated entities
Industry	33, 34, 36, and 37	Facilities engaging in cleaning operations using halogenated solvent cleaning machines.

This list is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. This list includes the types of entities that the EPA is now aware could potentially be regulated by this action. Other types of entities not listed could also be affected. To determine whether your facility, company, or organization is regulated by this direct final rule, you should carefully examine the applicability criteria in § 63.460 of the promulgated rule. If you have any questions regarding the applicability of this direct final rule to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Organization of This Document

The information presented in this preamble is organized as follows:

I. Background
A. Why Is EPA Amending the NESHAP for Halogenated Solvent Cleaning?
B. What Is the Purpose of This Direct Final Rule?
C. Does This Rule Apply to Me?
D. Do the Changes in Today's Direct Final Rule Apply to My Machines?
II. New Requirements for Continuous Web Cleaning Machines
A. How Do I Know if My Machine is a Continuous Web Cleaning Machine?
B. What Changes Impact My Continuous Web Cleaning Machines?
C. How Did EPA Develop These Changes?
D. How Do I Know if My Machine Is ''New'' or an ''Existing'' Continuous Web Cleaning Machine?
E. When Must I Comply With These New Requirements?
III. Other Changes
A. What Change Is EPA Making That Applies to My Transformer Cleaning Operations?
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B. Executive Order 12866: Regulatory Planning and Review
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E. Unfunded Mandates Reform Act
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G. Paperwork Reduction Act
H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
I. Submission to Congress and the Comptroller General
J. National Technology Transfer and Advancement Act

I. Background

A. Why Is EPA Amending the NESHAP for Halogenated Solvent Cleaning?

The EPA promulgated the halogenated solvent cleaning (HSC) NESHAP on December 2, 1994. That rule included requirements for batch and in-line cleaning machines and included both control device and work practice requirements. A batch cleaning machine is defined in the HSC NESHAP as ''a solvent cleaning machine in which individual parts or sets of parts move through the entire cleaning cycle before new parts are introduced.'' Inherent in some of the requirements is the understanding that the part or set of parts stops at one or various points in the machine for cleaning and for removal of cleaned parts. In contrast, an in-line cleaning machine (or continuous cleaning machine) is defined in the HSC NESHAP as ''a solvent cleaning machine that uses an automated parts handling system, typically a conveyor, to automatically provide a continuous supply of parts to be cleaned.''

After promulgation, several industry groups raised concerns about how some cleaning machines would be classified under the rule. These commenters stated that some machines did not clearly and completely fit into any of the categories of cleaning machines included in the HSC NESHAP. The machines in question included movie film cleaning machines and machines used to clean strips, rods, and wire.

After some initial review, the EPA concluded that these issues warranted additional consideration. On May 5, 1998 (63 FR 24768), the EPA issued an immediate stay of compliance for the continuous web cleaning machines until August 3, 1998. In that same action, the EPA proposed to extend the compliance date for these units for an additional year, to August 3, 1999, to allow for an equivalency determination. The EPA received comments on the proposed extension. One commenter expressed concern that the 1-year extension may not be sufficient time to review the data, complete the technical analysis, propose and promulgate an equivalency determination, and allow sufficient time for facilities to comply with the new requirements. The EPA agreed with these comments and on December 11, 1998 (63 FR 68397) extended the compliance date for continuous web cleaning machines to December 2, 1999.

B. What Is the Purpose of This Direct Final Rule?

This direct final rule does two things. First, it promulgates alternative compliance requirements for continuous web cleaning machines. A continuous web cleaning machine is a cleaning machine that cleans a continuous web part at speeds in excess of 11 feet per minute. Changes to the rule impacting continuous web cleaning machines are discussed in section II.A of this direct final rule. Second, this direct final rule makes two minor changes, discussed in section II.B, which are the only changes that impact cleaning machines other than continuous web cleaning machines.

C. Does This Rule Apply to Me?

You are subject to the HSC NESHAP if you are the owner or operator of a halogenated solvent cleaning machine. A halogenated solvent cleaning machine is any piece of equipment used to remove soil if the solvent used in the machine contains more than 5 percent in total of any of the following halogenated solvents: perchloroethylene; methylene chloride; 1,1,1-trichloroethane (also known as methyl chloroform); trichloroethylene; carbon tetrachloride; and chloroform.

D. Do the Changes in Today's Direct Final Rule Apply to My Machines?

The changes contained in today's direct final rule only apply to you if your machines meet any of the following criteria:

1. Halogenated solvent cleaning machines that are classified as continuous web cleaning machines. (Changes impacting these machines are discussed in section II.A.)
2. Halogenated solvent cleaning machines used to clean polychlorinated biphenyl (PCB) laden transformers. (A change impacting these machines is discussed in section II.B.)
3. Halogenated solvent cleaning machines that are steam-heated vapor cleaning machines. (The definition of continuous web cleaning machines and a change impacting these machines is discussed in section II.B.)

II. New Requirements for Continuous Web Cleaning Machines

A. How Do I Know if My Machine Is a Continuous Web Cleaning Machine?

A continuous web cleaning machine is a solvent cleaning machine in which parts such as film, coils, wire, and metal strips are cleaned at speeds in excess of 11 feet per minute. Parts are generally uncoiled, cleaned such that the same part is simultaneously entering and exiting the solvent application area of the solvent cleaning machine, and then recoiled or cut. For the purposes of this subpart, all continuous web cleaning machines are considered to be a subset

of in-line solvent cleaning machines. These units tend to be used in two distinct areas: (1) Movie film cleaning and (2) continuous strip, wire, or rod cleaning.

Movie Film Cleaning

The movie film cleaning industry typically uses a continuous web cleaning machine to clean the surfaces on large reels of film. Typically, a reel is loaded onto the machine and the film threaded through a series of rollers. The film is then either fed into a vat or past a series of spray nozzles that apply the chlorinated solvent onto the film. The film is then dried using air jets, cloth pads, or a combination of both.

Strip, Rod, or Wire Cleaning

This group of continuous web cleaning machines cleans a more diverse product group, including large flat pieces of metal, metal rods, and thin wires. The machines can be dip tanks, spray applications, or a combination. While the EPA has only currently identified continuous web cleaning machines used to clean metal products, these machines may clean nonmetal products which would also be covered by this rule.

The EPA considered both of the above types of continuous web cleaning machines when developing the changes discussed today.

B. What Changes Impact My Continuous Web Cleaning Machines?

The changes will enable you to comply with all of the requirements of the HSC NESHAP. The options are similar to the options for other in-line cleaning machines. The changes are equivalent to those codified at 40 CFR part 63, subpart T, and include new equivalent controls for some existing requirements and clarifications of the EPA's interpretation of existing requirements germane to continuous web cleaning machines. The changes account for the inherent differences between the solvent cleaning machines that were the basis for the HSC NESHAP promulgated in 1994 and continuous web cleaning machines. The changes to the rule that apply only to continuous web cleaning machines are:

1. An Alternative to the Requirement for a Maximum Parts Speed of 11 Feet per Minute and the Requirement for a Dwell Time in Some Options

You are not required to meet the speed and dwell requirements if your continuous web cleaning machine meets other specific requirements. These requirements include a properly designed, operated, and maintained system to eliminate visible carryout of solvent on your continuous web product. In addition, you must comply with the monitoring, recordkeeping, and reporting requirements for the controls that replace the hoist speed and dwell requirements.

2. A Change in the Alternative for Continuous Web Cleaning Machines Venting to a Carbon Adsorber

A properly designed and operated continuous web cleaning machine can comply with the new or existing source requirements by venting the exhaust from the enclosed cleaning chamber through a properly operated and maintained carbon adsorption system instead of one of the equipment combinations listed in the HSC NESHAP. However, the system used must be demonstrated to the Administrator's satisfaction to be equal to the MACT level of control established for the listed control combinations.

3. A Clarification That There is No Freeboard Ratio Requirement if Your Continuous Web Cleaning Machine Does Not Have an Exposed Sump

That is, if your continuous web cleaning machine has a remote reservoir, no freeboard ratio requirement applies.

4. A Clarification That the Ban on the Cleaning of Absorbent Materials Does Not Apply to Cloth Rollers Used in the Cleaning Process Inside Your Machine

However, you do have requirements that apply when you remove these rollers from the machine.

5. A Clarification on the Interpretation of Superheated Vapor Technology for Continuous Web Cleaning Machines

The new interpretation allows for any technology that raises the continuous web part above the boiling point of the solvent. A new term, superheated part technology, has been added to the rule to more clearly address this situation. Therefore, as with the HSC NESHAP promulgated in 1994, your specific compliance options in the amended HSC NESHAP depend on whether your cleaning machines are considered to be new or existing.

C. How Did EPA Develop These Changes?

The EPA evaluated all data received on continuous web cleaning machines from the industry. The EPA contacted some facilities for additional data and identified several facilities for site visits. The EPA conducted several site visits and was able to gather additional data on the unique design and operational requirements of continuous web cleaning machines. Based on these data, EPA evaluated how continuous web cleaning machines best fit into the HSC NESHAP promulgated in 1994 and identified changes to be made. The inability of some continuous web cleaning machines to comply with the rule is a result of differences between those machines and the cleaning machines used as the basis for the HSC NESHAP promulgated in 1994.

The first step in EPA's analysis was to determine whether existing compliance options could be used for continuous web cleaning machines. The only option available that did not include a maximum hoist speed requirement was the alternative standard included in § 63.464.

This option has only an overall solvent emission rate, with no design or work practice requirements. The EPA concluded that the continuous web cleaning machines were not candidates for the alternative standard. In addition, the overall solvent emission rates were established based on an infrequently used solvent cleaning machine, not on a continuous web cleaning machine. As the name suggests, continuous web cleaning machines tend to be operated on a continuous or near-continuous basis. Since compliance with this alternative standard was not viable, EPA then looked at the primary standards.

In general, continuous web cleaning machines could be brought into compliance with the requirements of the HSC NESHAP but for the following two requirements.

- The design requirement of § 63.463(a)(3) that ''each cleaning machine shall have an automated parts handling system capable of moving parts or parts baskets at a speed of 11 feet per minute or less from the initial loading of parts through the removal of cleaned parts.''
- The requirement for a ''dwell'' that is included in two of the four compliance options available for existing in-line cleaning machines.

The changes that were needed in the HSC NESHAP were due to potential issues with the following requirements:

- The design requirement of § 63.463(a)(2) that each ''cleaning machine shall have a freeboard ratio of 0.75 or greater.''
- The work practice requirement of § 63.463(d)(12) that ''sponges, fabric, wood, and paper products shall not be cleaned.''
- The design requirement for superheated vapor technology in one of the options for existing cleaning machines and two of the options for new cleaning machines.

Each of the changes deemed necessary to address these issues is discussed below.

1. Maximum Hoist Speed and Dwell Requirements

Continuous web cleaning machines are different from other solvent cleaning machines—they are designed to clean parts traveling at a high rate of speed. In addition, the ''part'' being cleaned, the continuous web part, is a long strip of material that is never totally within the parts cleaning machine. The part moves through the cleaning machine such that one end of the part exits the machine before the other end enters. Therefore, there is no opportunity to meet a dwell requirement.

When evaluating equivalency of alternative controls, it is important to understand the reason for the requirements in the original HSC NESHAP. Limiting part speed was required for two primary reasons:

- To limit liquid carryout on the part being cleaned caused by improper draining and improper cycle time.
- To limit the vapor disturbance or vapor carryout caused by parts moving through the solvent cleaning machine too quickly.

Similarly, a proper dwell time also limits carryout emissions. First, dwell allows the part extra time within the freeboard for liquid or vapor solvent to flash off and/or drain back into the solvent tank. Stopping below the vapor zone of a vapor cleaner, as required by a dwell under this rule, also tends to limit the speed that the part is traveling as it goes through the vapor zone. The dwell is particularly beneficial when the part has large pieces sticking out that can capture solvent liquid or vapor and remove it from the machine as the part is removed.

Based on observations made during the site visits to facilities with continuous web cleaning machines, EPA has concluded that properly operated squeegees and/or air knives are capable of controlling emissions to at least the same degree as a reduced parts speed for continuous web parts. Air knives and squeegee systems on a continuous web part remove essentially all of the solvent that remains on the part. These systems likely exceed the performance of a reduced hoist speed, in and of itself, because the effectiveness of a reduced hoist speed on emissions is dependent on other factors, such as the part shape and orientation. These air knives and squeegees work on continuous web cleaning machines to a higher efficiency than on traditional units because the part being cleaned is flat. Therefore, there is nothing to trap the solvent liquid or vapors.

In order to ensure that all of the emission reductions associated with reduced parts speed and a dwell are realized, however, you will need to minimize the openings for part entrance and exit into the cleaning machine. The EPA observed minimized entry and exit openings in all cases that were evaluated during the development of these alternatives.

As with any other control, improperly operated or maintained squeegees or air knives can quickly eliminate any potential emission reductions. A part exiting a well-maintained squeegee or air knife system will be visibly dry. However, a part exiting an improperly maintained machine would have a thin film of solvent left on the surface. This film evaporates quickly after exiting the machine, which results in a much larger solvent loss rate. The new requirements in this direct final rule include requirements that ensure proper operation of these carryout reducing devices.

2. Carbon Adsorption Units on Continuous Web Cleaning Machines

When the EPA evaluated continuous web cleaning machines, we noticed an inherent benefit of these cleaning machines over typical machine design. This difference was particularly noticeable on film cleaning machines. The portion of film cleaning machines where solvent is applied tends to be enclosed and then vented to prevent solvent contamination of the expensive film. In these machines, the area surrounding the film take-up reel is also within an enclosed area and is often vented as well. When solvent is being used, the doors to the machines are closed. The exhaust from these machines is often vented to a carbon adsorber. The overall effectiveness of the carbon adsorber in these applications far exceeded the overall control efficiency calculated for other solvent cleaning machines during the rule development. A control efficiency of 65 percent was used for carbon adsorbers when a machine was actively cleaning parts. When combined with other controls and accounting for times when the machine was not operating, the overall control efficiencies that were used as the basis for existing and new machines was 60 and 70 percent, respectively.

Based on the information gathered on film cleaning machines, the EPA has concluded that the use of a carbon adsorption system on a properly operated and maintained unit will ensure emission reductions that are at least as effective as the controls established as MACT in the promulgated rule. For example, one continuous web cleaning machine using a carbon adsorption system observed by the EPA cleaned over 3,500 square feet of product per gallon of solvent used. Therefore, the use of a carbon adsorption system demonstrated to provide an overall control effectiveness of 70 percent (*i.e.*, capture efficiency times removal efficiency) is an alternative to the promulgated options for continuous web cleaning machines.

3. Freeboard Ratio Requirements for Remote Reservoir Machines

The HSC NESHAP includes a design requirement for a freeboard ratio of at least 0.75 for all in-line cleaning machines. In two of the compliance options for new in-line cleaning machines, a freeboard ratio of 1.0 is required. However, some continuous web cleaning machines do not have an exposed sump. These remote reservoir continuous web cleaning machines are more similar to the remote reservoir batch cold cleaning machines. In the HSC NESHAP, batch cold cleaning machines that have a remote reservoir are excluded from the freeboard requirement that other batch cold cleaning machines must have.

The EPA has concluded that the same reasons that justify remote batch cold cleaning machines not being required to maintain a minimum freeboard ratio also apply to continuous web cleaning machines. In all of these machines, the primary cleaning mechanism is from solvent sprayed on the parts through nozzles. The solvent then typically drains into a sump that has minimal openings which in many cases are also covered. In all cases, the opportunity for evaporation and for air disturbances is minimized. Therefore, EPA has also concluded that the exclusion from a freeboard requirement should also apply to remote reservoir continuous web cleaning machines. This exclusion has been added to the rule.

4. Cleaning of Absorbent Materials

The prohibition on cleaning absorbent materials in a halogenated solvent cleaning machine may cause problems for some continuous web cleaning machines. This prohibition was included because any absorbent materials that were cleaned in the machine would be solvent laden when removed from the machine. Removal of solvent laden parts would be a large source of emissions. Some continuous web cleaning machines use some absorbent materials, such as cloth rollers, in the cleaning process.

The EPA did not intend to prohibit the use of absorbent materials as part of the cleaning mechanism in a machine. Since these absorbent materials would not be removed from the machine after each cleaning, no emissions from these materials would occur during each cleaning cycle. However, once these materials are removed from the cleaning machine, they would be solvent laden, and emissions would occur if the absorbent cleaning materials were not properly handled.

The ability to use absorbent materials as part of the cleaning machine is clarified in today's direct final rule. However, any rollers or other absorbent materials that are removed from continuous web cleaning machines must be treated as hazardous waste and disposed of as required by applicable hazardous waste rules.

5. Superheated Vapor Technology

The purpose of superheated technology is to heat the part(s) to evaporate even the thin layer of solvent film that can exist after solvent cleaning. This is typically achieved by the introduction of superheated vapor into an enclosed portion of a cleaner. The superheated vapor then heats the part(s) to above the boiling point of the solvent. Any solvent, even the typical solvent film, on the surface of a part is virtually eliminated by this process. The remaining problem for most cleaning machines is the vapor entrainment on the part(s).

This technique and its effective emission reductions are not dependent on external forces providing the heating (*i.e.*, vapors contacting a part to heat it). Therefore, any process that effectively raises the temperature of the part above the boiling point of the solvent should achieve the same effect. This would include any physical process that raises the temperature of the part itself.

For example, some of the continuous materials being cleaned are metal rods or wires. These parts are often sent through processes that reduce their circumference, such as through the use of a die. This process is generally exothermic and the part can become heated to several hundred degrees. If the temperature of the part is heated to above the boiling point of the solvent, the same emission reductions achieved by the superheated vapor technology should be obtained. In fact, by not reintroducing solvent, the emission reductions may actually increase. In today's direct final rule, a new term, superheated part technology, has been added as an alternative to superheated vapor technology in all options that include a superheated vapor requirement.

6. Additional Clarification for Primary Condensers

An additional issue arose during the evaluation of the equivalent control devices. While already included in the promulgated rule, EPA wishes to clarify a point concerning freeboard refrigeration devices on continuous web cleaning machines. The purpose of a primary condenser is to condense vapors that rise out of the boiling sump. On the other hand, a freeboard refrigeration device creates a cool air blanket to limit diffusion. Primary coils can serve as a freeboard refrigeration device under certain conditions for vapor cleaners. However, many continuous web cleaning machines are not vapor cleaning machines; therefore, no requirement for a primary condensing coil applies to these units. Even if the continuous web cleaning machines were vapor cleaning machines, the rule allows for primary coils to be considered a freeboard refrigeration device if the required temperature of the air blanket is created within the freeboard area. Therefore, the ability to use any type of cooling coils as a freeboard refrigeration device is emphasized and clarified for continuous web cleaning machines.

D. How Do I Know if My Machine is ''New'' or an ''Existing'' Continuous Web Cleaning Machine?

Machines are classified as either new or existing based on the HSC NESHAP proposed on November 29, 1993. Continuous web cleaning machines on which construction started before November 29, 1993 are existing affected sources. Machines on which construction started on November 29, 1993 or later are new affected sources.

E. When Must I Comply With These New Requirements?

You must comply with these requirements by December 12, 1999 for both your new and existing affected sources. This date was established in a **Federal Register** notice published on December 11, 1998 (63 FR 68397).

III. Other Changes

A. What Change Is EPA Making That Applies to My Transformer Cleaning Operations?

The EPA has recently become aware of a potential conflict between the HSC NESHAP and some specific Toxic Substances Control Act (TSCA) permits. Some facilities clean transformers contaminated with PCBs using batch cold halogenated solvent cleaning machines. The cleaning of these PCB-laden transformers is covered under TSCA permits, which include requirements to ensure proper draining and proper disposal of all materials. These transformers often include absorbent materials (*i.e.*, cardboard). The HSC NESHAP requirements for cold cleaning machines state that ''Sponges, fabric, wood, and paper shall not be cleaned.'' (§ 63.462(c)(8)).

It is not EPA's intent to prohibit the proper decontamination operation for PCB-laden transformers. The intent of this requirement in the HSC NESHAP is to reduce the amount of solvent loss due to improper cleaning of absorbent materials, such as rags and cloths. The EPA has reviewed the requirements in an example permit of a facility conducting decontamination of these transformers and concluded that TSCA permits should adequately ensure that the intent of the HSC NESHAP is met for these operations. For example, these permits have sufficient requirements for proper draining and disposal of the transformers. Therefore, EPA is adding an exclusion for cleaning absorbent materials in PCB-laden transformers, in compliance with a permit issued under TSCA, in this direct final rule.

B. What Changes Impact My Steam-Heated Vapor Cleaning Machines?

Steam-heated vapor cleaning machines will no longer be required to have a device that shuts off the sump heat if the liquid level drops to the sump heater coils (§ 63.463(a)(4)). This requirement was included in the HSC NESHAP for all machines. However, since the promulgation of the HSC NESHAP, EPA has determined that this device is not necessary for steam-heated machines.

The lowest decomposition temperature of the chlorinated solvents subject to this rule is 788 degrees Fahrenheit (420 degrees Celsius). A steam-heated unit will never heat the solvent to 788 degrees Fahrenheit (420 degrees Celsius). Therefore, a switch that turns off the sump heat when the solvent layer reaches the heating coils is an unnecessary expense. Consequently, the requirement for low-level sump turn-off switches has been removed for steam-heated solvent cleaning machines.

IV. Impacts

The changes contained in this direct final rule are corrections, clarifications, and equivalent compliance alternatives and do not change the intended coverage of the HSC NESHAP (subpart T). These changes will not affect the estimated emission reductions or the

control costs for these rules. These clarifications and corrections should make it easier for owners and operators of affected sources, and for local and State authorities, to understand and implement the requirements in subpart T. The equivalent compliance alternatives will make it possible for owners and operators of continuous web cleaning machines to comply with all requirements of subpart T.

V. Administrative Requirements

A. Docket

The docket number for this rulemaking is A–92–39. The docket is an organized and complete file of information compiled by the EPA in the development of this rulemaking. The docket is a dynamic file because material is added throughout the rulemaking development. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the proposed and promulgated standards and their preambles, the docket contains the record in the case of judicial review. (See section 307(d)(7)(A) of the Clean Air Act.)

B. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the EPA must submit significant regulatory actions to the Office of Management and Budget (OMB) for review. The Executive Order defines ''significant regulatory action'' as one that OMB determines is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this direct final rule does not qualify as a ''significant regulatory action'' under the terms of Executive Order 12866 and, therefore, is not subject to review by OMB.

C. Executive Order 12875: Enhancing Intergovernmental Partnerships

Under Executive Order 12875, the EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments or the EPA consults with those governments. If the EPA complies by consulting, Executive Order 12875 requires the EPA to provide to OMB a description of the extent of the EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires the EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's direct final rule does not create a mandate on State, local, or tribal governments. This direct final rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this direct final rule.

D. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, the EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments or the EPA consults with those governments. If the EPA complies by consulting, Executive Order 13084 requires the EPA to provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of the EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires the EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

This direct final rule does not impose any duties or compliance costs on Indian tribal governments. Further, the direct final rule provided herein does not significantly alter the control standards imposed by the HSC NESHAP for any source, including any that may affect communities of the Indian tribal governments. Hence, today's direct final rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this direct final rule.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act (UMRA) of 1995, Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, the EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires the EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows the EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before the EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of the EPA regulatory proposals with significant Federal intergovernmental mandates, and

informing, educating, and advising small governments on compliance with the regulatory requirements.

The EPA has determined that this direct final rule 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 in any 1 year, and that this direct final rule does not significantly or uniquely impact small governments, because it contains no requirements that apply to such governments or impose obligations upon them. The EPA has not prepared a budgetary impact statement or specifically addressed the selection of the least costly, most cost-effective, or least burdensome alternative. In addition, because small governments will not be significantly or uniquely affected by this rule, the EPA is not required to develop a plan with regard to small governments. Therefore, the requirements of the UMRA do not apply to this direct final rule.

F. Regulatory Flexibility/Small Business Regulatory Enforcement Fairness Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601, *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, requires the EPA to give special consideration to the effect of Federal regulations on small entities and to consider regulatory options that might mitigate any such impacts. The EPA must prepare a regulatory flexibility analysis unless the EPA certifies 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 small government jurisdictions.

This direct final rule would not have a significant impact on a substantial number of small entities because it clarifies and makes corrections to the promulgated HSC NESHAP, but imposes no additional regulatory requirements on owners or operators of affected sources.

G. Paperwork Reduction Act

The information collection request (ICR) was submitted to the OMB under the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*) at the time this rule was originally promulgated. The amendments to the HSC NESHAP contained in this direct final rule will have no impact on the information collection burden estimates made previously. Therefore, the ICR has not been revised.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that the EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the EPA must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the EPA.

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, so that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This direct final rule is not subject to Executive Order 13045 because it is not an ''economically significant'' regulatory action as defined by Executive Order 12866, and it is based on technology performance rather than health or risks that may disproportionately affect children.

I. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801, *et seq.*, as added by the SBREFA of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this direct final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to publication of this direct final rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This direct final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

J. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995, Public Law 104–113, section 12(d) (15 U.S.C. 272 note), directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by one or more voluntary consensus standards bodies. The NTTAA requires the EPA to provide Congress, through OMB, with explanations when the EPA decides not to use available and applicable voluntary consensus standards.

This action does not involve the proposal of any new technical standards. The EPA welcomes comments on this aspect of the direct final rule and, specifically, invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

As part of a larger effort, the EPA is undertaking a project to cross-reference existing voluntary consensus standards on testing, sampling, and analysis with current and future EPA test methods. When completed, this project will assist the EPA in identifying potentially applicable voluntary consensus standards which can then be evaluated for equivalency and applicability in determining compliance with future regulations.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Continuous web cleaning, Film cleaning, Halogenated solvent cleaning machines, Hazardous substances.

Dated: August 6, 1999.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows.

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart T—National Emission Standards for Halogenated Solvent Cleaning

2. Amend § 63.461 by adding, in alphabetical order, definitions for ''air knife system,'' ''remote reservoir continuous web cleaning machine,'' ''squeegee system,'' and ''superheated

part technology,'' and by revising the definition of ''continuous web cleaning machine'' to read as follows:

§ 63.461 Definitions.

* * * * *

Air knife system means a device that directs forced air at high pressure, high volume, or a combination of high pressure and high volume, through a small opening directly at the surface of a continuous web part. The purpose of this system is to remove the solvent film from the surfaces of the continuous web part.

* * * * *

Continuous web cleaning machine means a solvent cleaning machine in which parts such as film, coils, wire, and metal strips are cleaned at speeds in excess of 11 feet per minute. Parts are generally uncoiled, cleaned such that the same part is simultaneously entering and exiting the solvent application area of the solvent cleaning machine, and then recoiled or cut. For the purposes of this subpart, all continuous web cleaning machines are considered to be a subset of in-line solvent cleaning machines.

* * * * *

Remote reservoir continuous web cleaning machine means a continuous web cleaning machine in which there is no exposed solvent sump. In these units, the solvent is pumped from an enclosed chamber and is typically applied to the continuous web part through a nozzle or series of nozzles. The solvent then drains from the part and is collected and recycled through the sump, allowing no solvent to pool in the work or cleaning area.

* * * * *

Squeegee system means a system that uses a series of pliable surfaces to remove the solvent film from the surfaces of the continuous web part. These pliable surfaces, called squeegees, are typically made of rubber or plastic media, and need to be periodically replaced to ensure continued proper function.

* * * * *

Superheated part technology means a system that is part of the continuous web cleaning process that heats the continuous web part either directly or indirectly to a temperature above the boiling point of the cleaning solvent. This could include a process step, such as a tooling die that heats the part as it is processed, as long as the part remains superheated through the cleaning machine.

* * * * *

3. Amend § 63.462 by revising paragraphs (c) introductory text and (c)(8) and adding paragraph (c)(9) to read as follows:

§ 63.462 Batch cold cleaning machine standards.

* * * * *

(c) Each owner or operator of a batch cold solvent cleaning machine complying with paragraphs (a)(2) or (b) of this section shall comply with the work and operational practice requirements specified in paragraphs (c)(1) through (c)(9) of this section, as applicable.

* * * * *

(8) Except as provided in paragraph (c)(9) of this section, sponges, fabric, wood, and paper products shall not be cleaned.

(9) The prohibition in paragraph (c)(8) of this section does not apply to the cleaning of porous materials that are part of polychlorinated biphenyl (PCB) laden transformers if those transformers are handled throughout the cleaning process, and disposed of in compliance with an approved PCB disposal permit issued in accordance with the Toxic Substances Control Act (TSCA).

* * * * *

4. Amend § 63.463 by revising paragraphs (a) introductory text, (c) introductory text, (d) introductory text, (e) introductory text and (e)(2) introductory text, and by adding paragraphs (e)(2)(viii) through (e)(2)(x) and paragraph (g) to read as follows:

§ 63.463 Batch vapor and in-line cleaning machine standards.

(a) Except as provided in § 63.464 for all cleaning machines and in paragraph (g)(3) of this section for continuous web cleaning machines, each owner or operator of a solvent cleaning machine subject to the provisions of this subpart shall ensure that each existing or new batch vapor or in-line solvent cleaning machine subject to the provisions of this subpart conforms to the design requirements specified in paragraphs (a)(1) through (a)(7) of this section.

* * * * *

(c) Except as provided in § 63.464 for all cleaning machines and in paragraph (g)(3) of this section for continuous web cleaning machines, each owner or operator of an existing or new in-line solvent cleaning machine shall comply with paragraph (c)(1) or (c)(2) of this section as appropriate. The owner or operator of a continuous web cleaning machine shall comply with the requirements of paragraph (g) in lieu of complying with this paragraph.

* * * * *

(d) Except as provided in § 63.464 for all cleaning machines and in paragraph (g)(3) of this section for continuous web cleaning machines, each owner or operator of an existing or new batch vapor or in-line solvent cleaning machine shall meet all of the following required work and operational practices specified in paragraphs (d)(1) through (d)(12) of this section, as applicable.

* * * * *

(e) Except as provided in paragraph (g)(4) of this section, each owner or operator of a solvent cleaning machine complying with paragraph (b), (c), or (g) of this section shall comply with the requirements specified in paragraphs (e)(1) through (e)(4) of this section.

* * * * *

(2) Determine during each monitoring period whether each control device used to comply with these standards meets the requirements specified in paragraphs (e)(2)(i) through (e)(2)(x) of this section.

* * * * *

(viii) If a superheated part system is used to comply with the standards for continuous web cleaning machines in paragraph (g) of this section, the owner or operator shall ensure that the temperature of the continuous web part is at least 10 degrees Fahrenheit above the solvent boiling point while the part is traveling through the cleaning machine.

(ix) If a squeegee system is used to comply with the continuous web cleaning requirements of paragraph (g)(3)(iii) of this section, the owner or operator shall comply with the following requirements.

(A) Determine the appropriate maximum product throughput for the squeegees used in the squeegee system, as described in § 63.465(f).

(B) Conduct the weekly monitoring required by § 63.466(a)(3). Record both the results of the visual inspection and the length of continuous web product cleaned during the previous week.

(C) Calculate the total amount of continuous web product processed since the squeegees were replaced and compare to the maximum product throughput for the squeegees.

(D) Ensure squeegees are replaced no later than when the maximum product throughput is attained.

(E) Redetermine the maximum product throughput for the squeegees if any solvent film is visible on the continuous web part immediately after it exits the cleaning machine.

(x) If an air knife system is used to comply with the continuous web cleaning requirements of paragraph (g)(3)(iii) of this section, the owner or operator shall comply with the following requirements.

(A) Determine the air knife parameter and parameter value that demonstrates to the Administrator's satisfaction that the air knife is properly operating. An air knife is properly operating if no visible solvent film remains on the continuous web part after it exits the cleaning machine.

(B) Maintain the selected air knife parameter value at the level determined in paragraph (a) of this section.

(C) Conduct the weekly monitoring required by § 63.466(a)(3).

(D) Redetermine the proper (air knife parameter) value if any solvent film is visible on the continuous web part immediately after it exits the cleaning machine.

(f) * * *

(g) Except as provided in § 63.464, each owner or operator of a continuous web cleaning machine shall comply with paragraphs (g)(1) through (g)(4) of this section for each continuous web cleaning machine.

(1) Except as provided in paragraph (g)(2) of this section, install, maintain, and operate one of the following control combinations on each continuous web cleaning machine.

(i) For each existing continuous web cleaning machine, the following control combinations are allowed:

(A) Superheated vapor or superheated part technology; and a freeboard ratio of 1.0 or greater.

(B) Freeboard refrigeration device; and a freeboard ratio of 1.0 or greater.

(C) Carbon adsorption system.

(ii) For each new continuous web cleaning machine, the following control combinations are allowed:

(A) Superheated vapor or superheated part technology; and a freeboard refrigeration device.

(B) A freeboard refrigeration device and a carbon adsorber.

(C) Superheated vapor or superheated part technology; and a carbon adsorber.

(2) If a carbon adsorber system can be demonstrated to the Administrator's satisfaction to have an overall control efficiency (*i.e.*, capture efficiency times removal efficiency) of 70 percent or greater, this system is equivalent to the options in paragraph (g) of this section. A system that is demonstrated to have an overall control efficiency of 70 percent or greater can be used in lieu of the control combinations in paragraph (g)(1) of this section.

(3) In lieu of complying with the provisions of § 63.463(a), the owner or operator of a continuous web cleaning machine shall comply with the following provisions:

(i) Each cleaning machine shall be designed or operated to meet one of the following control equipment or technique requirements:

(A) An idling and downtime mode cover, as described in § 63.463(d)(1)(i), that may be readily opened or closed, that completely covers the cleaning machine openings when in place, and is free of cracks, holes, and other defects.

(B) A reduced room draft as described in § 63.463(e)(2)(ii).

(C) Gasketed or leakproof doors that separate both the continuous web part feed reel and take-up reel from the room atmosphere if the doors are checked according to the requirements of § 63.463(e)(iii).

(ii) Each continuous web cleaning machine shall have a freeboard ratio of 0.75 or greater unless that cleaning machine is a remote reservoir continuous web cleaning machine.

(iii) Each cleaning machine shall have an automated parts handling system capable of moving parts or parts baskets at a speed of 3.4 meters per minute (11 feet per minute) or less from the initial loading of parts through removal of cleaned parts unless the cleaning machine is a continuous web cleaning machine that has a squeegee system or air knife system installed, maintained, and operated on the continuous web cleaning machine meeting the requirements of § 63.463(e).

(iv) Each vapor cleaning machine shall be equipped with a device that shuts off the sump heat if the sump liquid solvent level drops to the sump heater coils.

(v) Each vapor cleaning machine shall be equipped with a vapor level control device that shuts off sump heat if the vapor level in the vapor cleaning machine rises above the height of the primary condenser.

(vi) Each vapor cleaning machine shall have a primary condenser.

(vii) Each cleaning machine that uses a lip exhaust shall be designed and operated to route all collected solvent vapors through a properly operated and maintained carbon adsorber that meets the requirements of § 63.463(e)(2)(ii).

(4) In lieu of complying with the provisions of § 63.463(d), the owner or operator of a continuous web cleaning machine shall comply with the following provisions:

(i) Control air disturbances across the cleaning machine opening(s) by incorporating one of the following pieces of control equipment or techniques:

(A) Cover(s) to each solvent cleaning machine shall be in place during the idling mode and during the downtime mode unless either the solvent has been removed from the machine or maintenance or monitoring is being performed that requires the cover(s) in place.

(B) A reduced room draft as described in § 63.463(e)(2)(ii).

(C) Gasketed or leakproof doors or covers that separate both the continuous web part feed reel and take-up reel from the room atmosphere if the doors are checked according to the requirements of § 63.463(e)(iii).

(ii) Any spraying operations shall be conducted in a section of the solvent cleaning machine that is not directly exposed to the ambient air (*i.e.*, a baffled or enclosed area of the solvent cleaning machine) or within a machine having a door or cover that meets the requirements of paragraph (g)(4)(i)(C) of this section.

(iii) During start-up of each vapor cleaning machine, the primary condenser shall be turned on before the sump heater.

(iv) During shutdown of each vapor cleaning machine, the sump heater shall be turned off and the solvent vapor layer allowed to collapse before the primary condenser is turned off.

(v) When solvent is added or drained from any solvent cleaning machine, the solvent shall be transferred using threaded or other leakproof couplings and the end of the pipe in the solvent sump shall be located beneath the liquid solvent surface.

(vi) Each solvent cleaning machine and associated controls shall be maintained as recommended by the manufacturers of the equipment or using alternative maintenance practices that have been demonstrated to the Administrator's satisfaction to achieve the same or better results as those recommended by the manufacturer.

(vii) Waste solvent, still bottoms, sump bottoms, and waste absorbent materials used in the cleaning process for continuous web cleaning machines shall be collected and stored in waste containers. The closed containers may contain a device that would allow pressure relief, but would not allow liquid solvent to drain from the container.

(viii) Except as provided in paragraph (g)(4)(ix) of this section, sponges, fabric, wood, and paper products shall not be cleaned.

(ix) The prohibition in paragraph (g)(4)(viii) does not apply to absorbent materials that are used as part of the cleaning process of continuous web cleaning machines, including rollers and roller covers.

5. Amend § 63.465 by adding paragraph (f) to read as follows:

§ 63.465 Test methods.

* * * * *

(f) Each owner or operator of a continuous web cleaning machine using

a squeegee system to comply with § 63.463(g)(3) shall determine the maximum product throughput using the method in this paragraph. The maximum product throughput for each squeegee type used at a facility must be determined prior to December 2, 1999, the compliance date for these units.

(1) Conduct daily visual inspections of the continuous web part. This monitoring shall be conducted at the point where the continuous web part exits the squeegee system. It is not necessary for the squeegees to be new at the time monitoring is begun if the following two conditions are met:

(i) The continuous web part leaving the squeegee system has no visible solvent film.

(ii) The amount of continuous web that has been processed through the squeegees since the last replacement is known.

(2) Continue daily monitoring until a visible solvent film is noted on the continuous web part.

(3) Determine the length of continuous web product that has been cleaned using the squeegee since it was installed.

(4) The maximum product throughput for the purposes of this section is equal to the time it takes to clean 95 percent of the length of product determined in paragraph (f)(3) of this section. This time period, in days, may vary depending on the amount of continuous web product cleaned each day.

* * * * *

6. Amend § 63.466 by revising paragraph (a) introductory text and adding paragraphs (a)(3) through (a)(5) to read as follows:

§ 63.466 Monitoring procedures.

(a) Except as provided in paragraph (g) of this section, each owner or operator of a batch vapor or in-line solvent cleaning machine complying with the equipment standards in § 63.463(b)(1)(i), (b)(2)(i), (c)(1)(i), (c)(2)(i), (g)(1), or (g)(2) shall conduct monitoring and record the results on a weekly basis for the control devices, as appropriate, specified in paragraphs (a)(1) through (a)(5) of this section.

* * * * *

(3) If a squeegee system or air knife system is used to comply with the requirements of § 63.463(g), the owner or operator shall visually inspect the continuous web part exiting the solvent cleaning machine to ensure that no solvent film is visible on the part.

(4) Except as provided in paragraph (a)(5) of this section, if a superheated part system is used to comply with the requirements of § 63.463(g), the owner or operator shall use a thermometer, thermocouple, or other temperature measurement device to measure the temperature of the continuous web part while it is in the solvent cleaning machine. This measurement can also be taken at the exit of the solvent cleaning machine.

(5) As an alternative to complying with paragraph (a)(4) of this section, the owner or operator can provide data, sufficient to satisfy the Administrator, that demonstrate that the part temperature remains above the boiling point of the solvent at all times that the part is within the continuous web solvent cleaning machine. These data could include design and operating conditions such as information supporting any exothermic reaction inherent in the processing.

* * * * *

7. Amend § 63.467 by revising paragraph (a) introductory text and adding paragraphs (a)(6) and (a)(7) to read as follows:

§ 63.467 Recordkeeping requirements.

(a) Each owner or operator of a batch vapor or in-line solvent cleaning machine complying with the provisions of § 63.463 shall maintain records in written or electronic form specified in paragraphs (a)(1) through (a)(7) of this section for the lifetime of the machine.

* * * * *

(6) If a squeegee system is used to comply with these standards, records of the test required by § 63.466(f) to determine the maximum product throughput for the squeegees.

(7) If an air knife system is used to comply with these standards, records of the determination of the proper operating parameter and parameter value for the air knife system.

* * * * *

[FR Doc. 99–20861 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 69

Access Charges

CFR Correction

In Title 47 of the Code of Federal Regulations, parts 40 to 69, revised as of Oct. 1, 1998, on page 434, § 69.153 is corrected by removing the second paragraph (c) in the first column, and the second paragraph (c)(1) in the second column.

[FR Doc. 99–55523 Filed 8–18–99; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF DEFENSE

48 CFR Parts 204 and 252

[DFARS Case 99–D006]

Defense Federal Acquisition Regulation Supplement; Oral Attestation of Security Responsibilities

AGENCY: Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: The Director of Defense Procurement has issued a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to add a requirement for contractor employees that are cleared for access to certain classified information to attest orally that they will comply with the security requirements associated with the information.

EFFECTIVE DATE: August 19, 1999.

FOR FURTHER INFORMATION CONTACT: Ms. Melissa Rider, Defense Acquisition Regulations Council, PDUSD (A&T) DP (DAR), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062. Telephone (703) 602–4245; telefax (703) 602–0350. Please cite DFARS Case 99–D006.

SUPPLEMENTARY INFORMATION:

A. Background

This rule adds a new clause at DFARS 252.204–7005 for use in contracts requiring access to classified information. The new clause requires contractor employees that are cleared for access to Top Secret, Special Access Program, or Special Compartmented Information to attest orally that they will conform to the conditions and responsibilities imposed by law or regulation on those granted access to such information.

A proposed rule was published in the **Federal Register** on March 25, 1999 (64 FR 14424). Six sources submitted comments on the proposed rule. DoD considered all comments in the development of the final rule.

This rule was not subject to Office of Management and Budget review under Executive order 12866, dated September 30, 1993.

B. Regulatory Flexibility Act

DoD certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq., because the conditions and responsibilities addressed in the oral attestation are conditions and responsibilities that already are placed

on contractor personnel granted access to classified information. Any contractor costs related to compliance with the rule should be included in the contract price.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the rule does not impose any information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, et seq.

List of Subjects in 48 CFR Parts 204 and 252

Government procurement.

Michele P. Peterson,

Executive Editor, Defense Acquisition Regulations Council.

Therefore, 48 CFR Parts 204 and 252 are amended as follows:

1. The authority citation for 48 CFR Parts 204 and 252 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 204—ADMINISTRATIVE MATTERS

2. Section 204.404–70 is amended by adding paragraph (c) to read as follows:

204.404–70 Additional contract clauses.

* * * * *

(c) Use the clause at 252.204–7005, Oral Attestation of Security Responsibilities, in solicitations and contracts that include the clause at FAR 52.204–2, Security Requirements.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

3. Section 252.204–7005 is added to read as follow:

252.204–7005 Oral Attestation of Security Responsibilities.

As prescribed in 204.404–70(c), use the following clause: Oral Attestation of Security Responsibilities (Aug 1999)

(a) Contractor employees cleared for access to Top Secret (TS), Special Access Program (SAP), or Special Compartmented Information (SCI) shall attest orally that they will conform to the conditions and responsibilities imposed by law or regulation on those granted access. Reading aloud the first paragraph of Standard Form 312, Classified Information Nondisclosure Agreement, in the presence of a person designated by the Contractor for this purpose, and a witness, will satisfy this requirement. Contractor employees currently cleared for access to TS, SAP, or SCI may attest orally to their security responsibilities when being briefed into a new program or during their annual refresher briefing. There is no requirement to retain a separate record of the oral attestation.

(b) If an employee refuses to attest orally to security responsibilities, the Contractor shall deny the employee access to classified information and shall submit a report to the Contractor's security activity.

(End of clause)

[FR Doc. 99–21417 Filed 8–18–99; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

48 CFR Parts 204, 219, AND 253

[DFARS Case 99–D011/98–D017]

Defense Federal Acquisition Regulation Supplement; Fiscal Year 2000 Contract Action Reporting Requirements

AGENCY: Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: The Director of Defense Procurement has issued a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to address contract action reporting requirements for fiscal year 2000. The rule makes changes to the Individual Contracting Action Report and the Monthly Contracting Summary of Actions $25,000 or less.

EFFECTIVE DATE: October 1, 1999.

FOR FURTHER INFORMATION CONTACT: Ms. Melissa Rider, Defense Acquisition Regulations Council, PDUSD (A&T) DP (DAR), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062. Telephone (703) 602–4245; telefax (703) 602–0350. Please cite DFARS Case 99–D011/98–D017.

SUPPLEMENTARY INFORMATION:

A. Background

This final rule contains fiscal year 2000 requirements for completion of DD Form 350, Individual Contracting Action Report, and DD Form 1057, Monthly Contracting Summary of Actions $25,000 or less. DoD uses these forms to collect statistical data on its contracting actions. This rule adds requirements for reporting of contracting actions with HUBZone small business concerns and very small business concerns; actions under Federal Supply Schedule contracts and fixed-price-award-fee contracts; and actions that support contingency, humanitarian, or peacekeeping operations.

DD Forms 350 and 1057, and other forms prescribed by the DFARS, are not included in the Code of Federal Regulations, The forms are available electronically via the World Wide Web at http://web1.whs.osd.mil/icdhome/forms.htm

This rule was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

B. Regulatory Flexibility Act

This final rule does not constitute a significant revision within the meaning of FAR 1.501 and Public Law 98–577 and publication for public comment is not required. However, DoD will consider comments from small entities concerning the affected DFARS subparts in accordance with 5 U.S.C. 610. Such comments should cite DFARS Case 99–D011/98–D017.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the rule does not impose any information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 204, 219, and 253

Government procurement.

Michele P. Peterson,

Executive Editor, Defense Acquisition Regulations Council.

Therefore, 48 CFR Parts 204, 219, and 253 are amended as follows:

1. The authority citation for 48 CFR Parts 204, 219, and 253 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 204—ADMINSITRATIVE MATTERS

2. Section 204.670–2 is revised to read as follows:

204.670–2 Reportable contracting actions.

(a) Except as provided in paragraph (c) of this subsection, complete a DD Form 350 for the following types of contracting actions in accordance with the instructions in 253.204–70:

(1) Actions that obligate or deobligate more than $25,000, including actions executed by DoD for purchase of land, or rental or lease of real property, and excluding actions summarized on DD Form 1057 in accordance with paragraph (b)(2) of this subsection.

(2) Actions that obligate or deobligate $25,000 or less and are in designated industry group under the Small Business Competitiveness

Demonstration Program (see FAR subpart 19.10) or are under a very small business set-aside (see FAR subpart 19.9), except for—

(i) Actions of $500 or less;

(ii) Foreign military sales;

(iii) Orders or modifications under Federal schedules;

(iv) Actions with government agencies;

(v) Actions with non-U.S. business firms; and

(vi) Actions where the place of performance is other than the United States and its outlying areas.

(b) Except as provided in paragraph (c) of this subsection, summarize the following types of contracting actions on the monthly DD Form 1057 in accordance with the instructions in 253.204–71:

(1) Actions that obligate or deobligate $25,000 or less, except actions reported on DD Form 350 in accordance with paragraph (a)(2) of this subsection.

(2) Actions that obligate or deobligate more than $25,000, but not more than $200,000, and support—

(i) A contingency operation as defined in 10 U.S.C. 101(a)(13); or

(ii) A humanitarian or peacekeeping operation as defined in 10 U.S.C. 2302(7).

(c) Do not report the following types of contracting action on either the DD Form 350 or DD Form 1057:

(1) Imprest fund transactions, SF 44 purchases, and micro-purchases obtained through use of the Government-wide commercial purchase card.

(2) Transactions that cite only nonappropriated funds (Treat funds held in trust accounts for foreign governments as appropriated funds).

(3) Transactions for purchase of land, or rental or lease of real property, when the General Services Administration (GSA) executes the contracting action.

(4) Orders from GSA stock and the GSA Consolidated Purchase Program.

(5) Transactions that involve Government bills of lading or transportation requests, except orders placed under Regional Storage Management Office basic ordering agreements.

(6) Requisitions transferring supplies within or among the departments or agencies.

(7) Pursuant to 204.670–6(b), orders placed by other contracting activities against indefinite-delivery contracts awarded by the—

(i) Military Sealift Command;

(ii) Defense Fuel Supply Center for petroleum and petroleum products; or

(iii) Defense Supply Center, Richmond, for petroleum products

204.670–9 [Removed]

3. Section 204.670–9 is removed.

PART 219—SMALL BUSINESS PROGRAMS

219.1006 [Amended]

4. Section 219.1006 is amended in paragraph (d) by removing ''204.670–9'' and adding in its place ''204.670–2''.

PART 253—FORMS

5. Section 253.204–70 is revised to read as follows:

253.204–70 DD Form 350, Individual Contracting Action Report.

Policy on use of a DD Form 350 is in 204.670–2. This subsection contains instructions for completion of the DD Form 350.

(a) *Part A of the DD Form 350.* Part A identifies the report and the reporting activity. Complete all four blocks.

(1) Block A1, TYPE OF REPORT. Enter one of the following codes:

(i) *Code 0—Original.* Enter code 0 unless code 1 or code 2 applies.

(ii) *Code 1—Cancelling.* A cancelling action cancels an existing DD Form 350 in accordance with departmental data collection point instructions.

(iii) *Code 2—Correcting.* A correcting action corrects an existing DD Form 350 action in accordance with departmental data collection point instructions.

(2) Block A2, REPORT NO. Enter the six-position local control number (see 204.670–3(a)(4)). If block A1 is coded 1 or 2, use the prior report number rather than a new one.

(3) BLOCK A3, CONTRACTING OFFICE CODE. Enter the code assigned the contracting office by the departmental data collection point shown in 204.670–1(c).

(4) BLOCK A4, NAME OF CONTRACTING OFFICE. Enter sufficient detail to establish the identity of the contracting office.

(b) *Part B of the DD Form 350.* Part B identifies the transaction.

(1) BLOCK B1, CONTRACT IDENTIFICATION INFORMATION. Do not leave any parts of Block B1 blank.

(i) BLOCK B1A, CONTRACT NUMBER.

(A) Enter—

(*1*) The DoD contract number; or

(*2*) For orders under contracts awarded by other Federal agencies, the contract number of that Federal agency as it appears in the contractual instrument.

(B) Do not leave spaces between characters, and do not enter dashes, slants, or any other punctuation marks.

(C) The DoD contract number is the basic (13 alphanumeric character) procurement instruction identification number (PIIN) that was assigned in accordance with 204.7001 or constructed under an exception permitted by 204.7000. Do not enter any supplementary procurement instrument identification numbers as part of the contract number (these go in block B2).

(ii) BLOCK B1B, ORIGIN OF CONTRACT. Enter the code that indicates the agency that originated/assigned the contract number.

(A) *Code A—DoD.*

(B) *Code B—NASA.*

(C) *Code C—Other Non-DoD Agency.*

(2) BLOCK B2, MODIFICATION, ORDER OR OTHER ID NUMBER. Enter the supplementary procurement instrument identification number (if there is one) that was assigned in accordance with 204.7004 or as permitted by 204.7000. It can be up to 19 characters. Usually calls and orders have a four-position number (see 204.7004(d)); modifications to contracts and agreements have a six-position modification number (see 204.7004(c)); and modifications to calls and orders have a two-position modification number (see 204.7004(e)). When reporting modifications to calls and orders, enter both the call/order number and the modification number.

(3) BLOCK B3, ACTION DATE.

(i) Enter the year, month, and day of the effective date for fiscal obligation purposes.

(ii) Enter four digits for the year, two digits for the month, and two digits for the day. Use 01 through 12 for January through December. For example, enter January 2, 2003, as 20030102.

(4) BLOCK B4, COMPLETION DATE.

(i) Enter the year, month, and day of the last contract delivery date or the end of the performance period. If the contract is incrementally funded, report the completion date for the entire contract. Report the completion date associated with an option quantity when the option is exercised.

(ii) Enter four digits for the year, two digits for the month, and two digits for the day. Use 01 through 12 for January through December. For example, enter January 2, 20003, as 20030102.

(5) BLOCK B5, CONTRACTOR IDENTIFICATION INFORMATION.

(i) Use data that relates to the contractor whose name and address appear in the contract document (Block 7 of the SF 26, Award/Contract; Block 8 of the SF 30, Amendment of Solicitation/Modification of Contract; Block 15A of the SF 33, Solicitation, Offer and Award; or Block 9 of the DD Form 1155, Order for Supplies or Services), except—

(A) For contracts placed with the Small Business Administration under Section 8(a) of the Small Business Act, use data that relates to the company that will be performing the work;

(B) For Federal schedule orders, use data that applies to the contractor whose name appears on the schedule (not the data for the agent to whom orders may be sent); and

(C) For contracts with the Canadian Commercial Corporation (CCC), use data for the appropriate CCC office.

(ii) Some of the parts of Block B5 may not apply to the action being reported. Follow the instructions for each part.

(A) BLOCK B5A, CONTRACTOR IDENTIFICATION NUMBER.

(1) Enter the contractor's 9-position Data Universal Numbering System (DUNS) number or 13-position DUNS+4 number (see FAR 4.602(d) and 4.603 and DFARS subpart 204.73).

(2) For all actions with UNICOR/Federal Prison Industries, use DUNS number 62–662–7459.

(3) For U.S. Army Contracting Command, Europe, consolidated reporting of vouchers for utilities from municipalities, use DUNS number 15–390–6193 (see 204.670–6(b)(1)).

(B) BLOCK B5B, GOVERNMENT AGENCY. Enter one of the following codes:

(1) Code Y—Yes. Enter code Y when the contractor is a Federal/State/local government agency of the United States and outlying areas (see 204.670–1(d)). Do not use code Y when the government agency is an educational institution.

(2) Code N—No. Enter code N when code Y does not apply.

(C) BLOCK B5C, CAGE, CODE. Enter the 5-position Commercial and Government Entity (CAGE) code that identifies the contractor plant or establishment. If the CAGE code is not already available in the contracting office and the apparent awardee does not respond to the provision at 252.204–7001, Commercial and Government Entity (CAGE) Code Reporting, use the procedures at 204.7202–1 to obtain one.

(D) BLOCK B5D, CONTRACTOR NAME AND DIVISION NAME. Enter the contractor's name as stated in the offer and resultant contract. Include its division name.

(E) BLOCK B5E, CONTRACTOR ADDRESS. Enter the contractor's address as stated in the offer and resultant contract. Include street address (and/or P.O. Box), city/town, state/country, and ZIP code, if applicable. Do not enter foreign postal codes.

(F) BLOCK B5F, TIN. Enter the contractor's taxpayer identification number (see FAR Subpart 4.9). Leave Block B5F blank if the contractor is)

(1) Registered in the Central Contractor Registration database (see Subpart 204.73);

(2) A nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the trade or business in the United States; and does not have an office or place of business or a fiscal paying agent in the United States;

(3) An agency or instrumentality of a foreign government; or

(4) An agency or instrumentality of the Federal Government.

(G) BLOCK B5G, PARENT TIN. Enter the contractor's parent company (common parent) TIN (see FAR Subpart 4.9 and 52.204–3. If the contractor does not have a parent company or the parent company meets the exemption for Block B5F, leave Block B5G blank.

(H) BLOCK B5H, PARENT NAME. If a parent company TIN is entered in Block B5G, enter in Block B5H the name of the parent company (common parent). Leave Block B5H blank if there is no parent company or the parent company is exempted from the requirement to have a TIN.

(6) BLOCK B6, PRINCIPAL PLACE OF PERFORMANCE.

(i) The place, or places, where the contract will be performed may be specified by the Government or listed by the contractor in response to the solicitation provision at FAR 52.214—14, Place of Performance—Sealed Bidding, or FAR 52.215–6, Place of Performance. Use data for the contractor's principal place of performance, which is generally the—

(A) Final assembly point for items manufactured under supply contracts;

(B) Location from where shipments from stock are made under supply contracts;

(C) Actual construction site for construction contracts;

(D) Planned construction site for architect-engineer contracts;

(E) Place of mining for mined supplies; or

(F) Place (including military installations) where a service is performed for service contracts.

(ii) When there is more than one location for any of paragraphs (b)(6)(i)(A) through (F) of this subsection (e.g., more than one construction site), use the location involving the largest dollar amount of the acquisition. Do not show more than one location in Block B6.

(iii) If places of performance are too varied or not known, or if commercial procedures were used, enter the contractor's home office location.

(iv) Follow the instructions for each part of Block 6 that applies to the action being reported.

(A) BLOCK B6A, CITY OR PLACE CODE.

(1) For places in the United States and outlying areas, enter the numeric place code, which can be found in the Federal Information Processing Standards (FIPS) Publication (PUB) 55, Guideline: Codes for Named Populated Places, Primary Country Divisions, and Other Locational Entities of the United States and Outlying Areas. Leave Block B6A blank for places outside the United States and outlying areas.

(2) If the city or locality is not listed, look in FIPS PUB 55 for the county code of the principal place of performance. Enter that code in Block B6A. Use 50000 for Washington, DC, with a State code of 11.

(3) Paragraph 5.2, Entry Selection With the Aid of the Class Code, of FIPS PUB 55 will help in selecting the correct code. Sometimes, a class code should be used in addition to a place code to accurately identify the place of performance. Do not use place codes when the first position of the class code is X or Z.

(B) BLOCK B6B, STATE OR COUNTRY CODE.

(1) For places in the United States and outlying areas, enter the numeric State code, which can be found in FIPS PUB 55 or FIPS Pub 5, Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States and Associated Areas.

(2) For places outside the United States and outlying areas, enter the alpha country code from FIPS PUB 10, Countries, Dependencies, Areas of Special Sovereignty, and Their Principal Administrative Divisions.

(C) BLOCK B6C, CITY OR PLACE AND STATE OR COUNTRY NAME. Enter the name of the principal place of performance. Do not leave block B6C blank.

(7) BLOCK B7, TYPE OBLIGATION. Enter one of the following codes:

(i) *Code 1—Obligation.* Enter code 1 if the contracting action obligates funds.

(ii) *Code 2—Deobligation.* Enter code 2 if the contracting action deobligates funds.

(8) BLOCK B8, TOTAL DOLLARS. Enter the net amount of funds (whole dollars only) obligated or deobligated by the contracting action. Do not leave Block B8 blank.

(9) BLOCK B9, FOREIGN MILITARY SALE. Enter one of the following codes. If only part of the contracting action is a foreign military sale, separately report the parts (see 204.670–6(c)).

(i) *Code Y—Yes.* Enter code Y when the contracting action is under a foreign military sales arrangement, or under any other arrangement when a foreign

country or international organization is bearing the cost of the acquisition.

(ii) *Code N—No.* Enter code N when code Y does not apply.

(10) BLOCK B10, MULTIYEAR CONTRACT. Enter one of the following codes:

(i) *Code Y—Yes.* Enter code Y when the contracting action is a multiyear contract as defined at FAR 17.103. Do not report contracts containing options as multiyear unless the definition at FAR 17.103 applies to the contract.

(ii) *Code N—No.* Enter code N when code Y does not apply.

(11) BLOCK B11, TOTAL MULTIYEAR VALUE. Enter the total estimated multiyear contract value (in whole dollars) only at the time of initial obligation of multiyear funds for a new letter contract or a new definitive contract (Block B13A is coded 1 or 3 and Block B13D is blank). For all other codes in Block B13A, enter a numeric value of zero in Block B11.

(12) BLOCK B12, PRINCIPAL PRODUCT OR SERVICE. B12 contains five parts. Do not leave any parts of Block B12 blank.

(i) BLOCK B12A, FSC or SVC CODE. Enter the 4-character Federal supply classification (FSC) or service code that describes the contract effort. To find the code, look in Section I of the Department of Defense (DoD) Procurement Coding Manual (MN02). There are three categories of codes to choose from. In some cases, use a 4-character code from a list of 4-character codes; in other cases, construct a code using the instructions in the Manual. If more than one category or code applies to the contracting action, enter the one that best identifies the product or service representing the largest dollar value.

(A) *Supplies.* If the contracting action is for the purchase (not lease or rental) of supplies, enter an FSC code in block B12A. FSC codes are all numeric. Look in Section I, Part C, of the DoD Procurement Coding Manual (MN02). The Department of Defense Federal Supply Classification Cataloging Handbook (H2) may also help with the correct 4-digit code.

(B) *Services.* If the contracting action is for services (except research, development, test, and evaluation), construction, or lease or rental of equipment or facilities, enter a service code in block B12A.

(C) *Research, Development, Test, and Evaluation. (RDT&E).* If the contracting action is for RDT&E (as defined in FAR 35.001 and 235.001), enter an RDT&E code in block B12A. Look in Section I, Part A, of the DoD Procurement Coding Manual (MN02). All RDT&E codes should begin with the letter ''A.'' Do not use an RDT&E code for—

(*1*) Purchase, lease, or rental of equipment, supplies, or services separately purchased in support of RDT&E work, even if RDT&E funds are cited. Instead, use an FSC or Service code under the instructions in paragraph (b)(12)(i)(A) or (B) of this subsection; or

(*2*) Orders under Federal schedule contracts. Instead, uses an FSC or Service code under the instructions in paragraph (b)(12)(i)(a) or (B) of this subsection.

(ii) BLOCK B12B, DOD CLAIMANT PROGRAM CODE. Enter a code that identifies the commodity described in Block B12E. These codes are in Section III of the DoD Procurement Coding Manual (MN02). If more than one code applies to the contracting action, enter the one that best identifies the product or service representing the largest dollar value. If the description in Block B12E is for—

(A) Research and development (R&D), enter the code that best represents the objective of the R&D. For example, if the objective of the R&D is a guided missile, enter code A20. If the R&D cannot be identified to any particular objective, enter code S10;

(B) Ship repair, inspect and repair as necessary (IRAN), modification of aircraft, overhaul of engines, or similar maintenance, repair, or modification services, enter the code that best identifies the program;

(C) Equipment rental (including rental of automatic data processing equipment), enter code S10;

(D) Utility services, enter code S10;

(E) Services that cannot be identified to any listed program, enter code S10; or

(F) Supplies or equipment that cannot be identified to any listed program, enter code C9E.

(iii) BLOCK B12C, PROGRAM, SYSTEM OR EQUIPMENT CODE.

(A) Enter a code that describes the program, weapons system, or equipment. These codes are in Section II of the DoD Procurement Coding Manual (MN02). If there is no code that applies to the contracting action, enter three zeros. If more than one code applies to the action, enter the one that best identifies the product or service representing the largest dollar value.

(B) If the contracting action is funded by the Ballistic Missile Defense Organization, enter code CAA.

(C) If the contracting action supports environmental cleanup programs, enter one of the codes listed in Section II of the DoD Procurement Coding Manual (MN02) under the heading ''Description and Use of Program Codes—Environmental Cleanup Programs.''

(D) Defense Logistics Agency activities must use the code assigned by the sponsoring military department.

(iv) BLOCK B12D, SIC CODE. Enter the standard industrial classification (SIC) code for the acquisition (as opposed to the SIC of the contractor). Use the SIC code in effect at the time of award. These codes are in the OMB Standard Industrial Classification Manual. If more than one code applies to the contracting action, enter the one that best identifies the product or service representing the largest dollar value.

(v) BLOCK B12E, NAME/DESCRIPTION. Enter the name or a brief description of the commodity or service. If the description is classified, enter only the word ''Classified.'' Do not, however, use ''Classified'' when a code name (e.g., Minuteman, Polaris, Trident, Pershing) or an identifying program number (e.g., WS–107A) can be used.

(13) BLOCK B13, KIND OF CONTRACTING ACTION. Some of the parts of Block B13 may not apply to the action being reported. Follow instructions for each part. When the contracting action is a modification, complete Blocks B13A an B13D.

(i) BLOCK B13A, CONTRACT/ORDER. Enter one of the following codes:

(A) *Code 1—Letter Contract.* Enter code 1 when the contracting action is a letter contract or a modification to a letter contract that has not been definitized.

(B) *Code 3—Definitive Contract.*

(1) Enter code 3 when the contracting action is the award or modification of a definitive contract or a modification that definitizes a contract. Code 3 includes the following:

(i) Definitive contract awards under the Small Business Administration 8(a) program.

(ii) Notices of award.

(iii) Lease agreements.

(iv) Indefinite-delivery-definite-quantity contracts (FAR 52.216–20).

(v) Indefinite-delivery-indefinite-quantity contracts (FAR 52.216–22) when funds are obligated by the contract itself.

(2) Code 3 excludes orders from the Procurement List (see codes 6 and 8).

(C) *Code 4—Order under an Agreement.* Enter code 4 when the contracting action is an order or definitization of an order under an agreement other than a blanket purchase agreement. Examples include an order exceeding $25,000 under a basic ordering agreement or a master ship repair agreement and a job order when

the contract is created by issuing the order. A call under a blanket purchase agreement associated with a Federal schedule (see FAR 8.404(b)(4)) is coded 6. A call under other blanket purchase agreements, pursuant to FAR 13.303, is coded 9. When the contracting action is a modification to an order described in code 4 instructions, enter code 4 in B13A.

(D) *Code 5—Order under Indefinite-Delivery Contract (IDC).* Enter code 5 when the contracting action is an order, including a task or delivery order, under an indefinite-delivery contract awarded by a Federal agency. For example, enter code 5 for an order under a GSA indefinite-delivery contract, such as a GSA area-wide contract for utility services, that is not a Federal schedule. When the contracting action is a modification to an order described in code 5 instructions, enter code 5 in B13A.

(E) *Code 6—Order/Call under Federal Schedule.* Enter code 6 if the contracting action is an order under a GSA or VA Federal Supply Schedule, or a call against a blanket purchase agreement established under a GSA or VA Federal Supply Schedule (see FAR 8.404). Code 6 includes orders under Federal Supply Schedules for items on the Procurement List. When the contracting action is a modification to an order or call described in code 6 instructions, enter code 6 in B13A.

(F) *Code 8—Order from Procurement List.* Enter code 8 if the contracting action is an action placed with Federal Prison Industries (UNICOR) or a JWOD Participating Nonprofit Agency in accordance with FAR Subpart 8.6 or 8.7. Use code 6 for orders from the Procurement List under Federal schedules. When the contracting action is a modification to an action described in code 8 instructions, enter code 8 in B13A.

(G) *Code 9—Purchase Order/Call.* Enter code 9 if the contracting action, including an action in a designated industry group under the Small Business Competitiveness Demonstration Program (see FAR Subpart 19.10), is an award pursuant to FAR Part 13, except when the contracting action is a blanket purchase agreement call pursuant to FAR 8.404(b)(4) (see code 6). When the contracting action is a modification to a purchase order or call described in code 9 instructions, enter code 9 in B13A.

(ii) BLOCK B13B, TYPE OF INDEFINITE-DELIVERY CONTRACT. If Block B13A is coded 3 and the ninth position of B1A is coded D, complete Block B13B. If Block B13A is coded 5, complete Block B13B. Otherwise, leave Block B13B blank.

(A) *Code A—Requirements Contract (FAR 52.216–21).*

(B) *Code B—Indefinite-Quantity Contract (FAR 52.216–22).*

(C) *Code C—Definite—Quantity Contract (FAR 52–216–20).*

(iii) BLOCK B13C, MULTIPLE/SINGLE AWARD IDC(S). If Block B13B is coded A, B, or C, complete Block B13C. Otherwise, leave Block B13C blank.

(A) *Code M—Multiple Award.* Enter code M if the contracting action is a task or delivery order under a multiple award indefinite-delivery contract.

(B) *Code S—Single Award.* Enter code S if the contracting action is a task or delivery order under a single award indefinite-delivery contract.

(iv) BLOCK B13D, MODIFICATION. If the contracting action is a modification, enter one of the following codes. Otherwise, leave Block B13D blank.

(A) *Code A—Additional Work (new agreement).* Enter code A when the contracting action is a bilateral supplemental agreement that obligates funds for additional work requiring a justification and approval (J&A).

(B) *Code B—Additional Work (other).* Enter code B when the contracting action is a modification of an existing contract (including a letter contract) that is not covered by code A or by codes C through H (see Code H for exercise of an option). Code B includes actions that—

(1) Initiate an incremental yearly buy under a multiyear contract;

(2) Amend a letter or other contract to add work that does not require a J&A; or

(3) Order under a priced exhibit or production list.

(C) *Code C—Funding Action.* Enter code C when the contracting action is a modification (to a letter or other contract) for the sole purpose of obligating or deobligating funds. This includes—

(1) Incremental funding (other than incremental yearly buys under multiyear contracts, which are coded B);

(2) Changes to the estimated cost on cost-reimbursement contracts;

(3) Repricing actions covering incentive price revisions;

(4) Economic price adjustments; and

(5) Initial citati9on and obligation of funds for a contract awarded in one fiscal year but not effective until a subsequent fiscal year.

(D) *Code D—Change Order.* Enter code D if the contracting action is a change order issued under the ''Changes,'' ''Differing Site Conditions,'' or similar clauses in existing contracts.

(E) *Code E—Termination for Default.* Enter code E if the contracting action is a modification that terminates all or part of the contract for default.

(F) *Code F—Termination for Convenience.* Enter code F if the contracting action is a modification that terminates all or part of the contract for convenience.

(G) *Code G—Cancellation.* Enter code G if the contracting action is a modification that cancels the contract. Do not use code G to cancel a prior DD Form 350 (see Block A1).

(H) *Code H—Exercise of an Option.* Enter code H if the contracting action is an exercise or an option.

(I) *Code J—Definitization of a Letter Contract.* Enter code J if the contracting action is the definitization of a letter contract, and enter code 3 in Block B13A.

(14) BLOCK B14, CICA APPLICABILITY. Enter one of the following codes:

(i) *Code A—Pre-CICA.* Enter code A if the action resulted from a solicitation issued before April 1, 1985. Modifications within the original scope of work of such awards and orders under pre-CICA indefinite-delivery type contracts also are coded A.

(ii) *Code B—CICA Applicable.* Enter code B if—

(A) The action resulted from a solicitation issued on or after April 1, 1985, or is a modification coded A in Block B13D issued on or after April 1, 1985; and

(B) Neither code C nor code D applies.

(iii) *Code C—Simplified Acquisition Procedures Other than FAR Subpart 13.5.* Enter code C if the action resulted from use of the procedures in FAR Part 13, other than those in Subpart 13.5.

(iv) *Code D—Simplified Procedures Pursuant to FAR Subpart 13.5.* Enter code D if the action resulted from use of the procedures in FAR Subpart 13.5.

(c) *Part C of the DD Form 350.*

(1) Part C gathers data concerning contracting procedures, use of competition, financing, and statutory requirements other than socioeconomic (which are in Part D).

(2) Do not complete part C if the contracting action is an action with a government agency, i.e., Block B5B (Government Agency) is coded Y (Yes). If Block B13A is coded 6, do not complete any blocks in Part C except Block C3, and Blocks C13A and C13B when they apply.

(3) In completing Part C, the codes to be used described either the contracting action being reported or the original contract, depending on the codes reported in Blocks B13A and B13D.

(i) If Block B13A is coded 1, 2, 3, 4, 6, or 9 and Block B13D is coded A or is blank, code the blocks in Part C with

reference to the action being reported. Otherwise, code the blocks with reference to the original contract.

(ii) If there are no codes for the original contact because a DD Form 350 was not required at the time, the original action is no longer available, the definition of the original code has changed, or a data element has been added to the system after the original contract report, use codes that best describe the original contracting action.

(4) Complete Part C blocks as follows:

(i) BLOCK C1, SYNOPSIS. Enter one of the following codes:

(A) *Code A—Synopsis Only.* Enter code A if only a synopsis of the proposed action was prepared and transmitted to the Commerce Business Daily in accordance with FAR subpart 5.2.

(B) *Code B—Combined Synopsis/Solicitation.* Enter code B if a combined synopsis/solicitation of the proposed action was prepared and transmitted to the Commerce Business Daily in accordance with FAR subpart 5.2 and 12.603.

(C) *Code N—No.* Enter code N if a synopsis was not prepared.

(ii) BLOCK C2, REASON NOT SYNOPSIZED. Enter one of the following codes if Block C1 is coded N. Otherwise, leave Block C2 blank.

(A) *Code A—Urgency.* Enter code A if the action was not synopsized due to urgency (see FAR 6.302–2).

(B) *Code B—Use of FACNET.* Enter code B if the action was not synopsized because the acquisition was made through FACNET or another means that provided access to the notice of proposed action through the single, Governmentwide point of entry (see FAR 5.202(a)(13)).

(C) *Code Z—Other Reason.* Enter code Z if the action was not synopsized due to some other reason.

(iii) BLOCK C3, EXTENT COMPETED. Enter one of the following codes:

(A) *Code A—Competed Action.* Enter code A when—

(1) The contracting action is an action under a Federal schedule contract (Block B13A is coded 6);

(2) Competitive procedures were used to fulfill the request for full and open competition (see FAR subpart 6.1);

(3) Full and open competition procedures after exclusion of sources were used in order to establish or maintain alternative sources, to set aside an acquisition for small business or HUBZone small business, or to compete Section 8(a) awards (see FAR subpart 6.2);

(4) Statutory authorities for other than full and open competition were used (see FAR subpart 6.3) and more than one offer was received (if only one offer was received, use code D);

(5) The contracting action resulted from a contract awarded prior to the Competition in Contracting Act that used two-step sealed bidding or other sealed bidding, or that was negotiated competitively; or

(6) Simplified acquisition procedures were used and competition was obtained.

(B) *Code B—Not Available for Competition.* Enter code B for—

(1) Awards for utilities or utility systems, excluding long distance telecommunications services, when only one supplier can furnish the service (see FAR 6.302–1(b)(3);

(2) Brand name commercial products for authorized resale;

(3) Acquisitions authorized or required by statue to be awarded to a specified source pursuant to FAR 6.302–5(b)(2) or (4), e.g., qualified nonprofit agencies employing people who are blind or severely disabled (see FAR subpart 8.7) or 8(a) program (see FAR subpart 19.8);

(4) International agreements and Foreign Military Sales when the acquisition is to be reimbursed by a foreign country that requires that the product or services be obtained from a particular firm as specified in official written direction such as a Letter of Offer and Acceptance; and

(5) Other contract actions when the Director of Defense Procurement has determined that there is no opportunity for competition.

(Note: Even though Part C is not completed for actions with a government agency, the database will automatically include these actions in the category of not available for competition.)

(C) *Code C—Follow-On to Competed Action.* Enter code C when the action pertains to an acquisition placed with a particular contractor to continue or augment a specific competed program when such placement was necessitated by prior acquisition decisions.

(D) *Code D—Not Competed.* Enter code D when codes A, B, and C do not apply.

(iv) BLOCK C4, SEA TRANSPORTATION. Enter one of the following codes when Block B1B is coded A, Block B5B is coded N, and block B13A is coded other than 9. Otherwise, leave Block C4 blank.

(A) *Code Y—Yes—Positive Response to DFARS 252.247–7022 or 252.212–7000(c)(2).* Enter code Y when the contractor's response to the provision at 252.247–7022, Representation of Extent of Transportation by Sea, or 252.212–7000(c)(2), Offeror Representations and Certifications—Commercial Items, indicates that the contractor anticipates that some of the supplies being provided may be transported by sea.

(B) *Code N—No—Negative Response to DFARS 252.247–7022 or 252.212–7000(c)(2).* Enter code N when the contractor's response to the provision at 252.247–7022 or 252.212–7000(c)(2) indicates that the contractor anticipates that none of the supplies being provided will be transported by sea.

(C) *Code U—Unknown—No Response or Provision Not Included in Solicitation.* Enter code U when the contractor did not complete the representation at 252.247–7022 or 252.212–7000(c)(2) or the solicitation did not include either provision.

(v) BLOCK C5, TYPE OF CONTRACT.

(A) If the action is a letter contract, including modifications and amendments to letter contracts, enter the code that describes the anticipated type of contract the letter contract will become when it is definitized.

(B) If there is more than one type of contract involved in the contracting action, enter the code that matches the type with the most dollars. If the type with the least dollars exceeds $500,000, fill out separate DD Forms 350 (with different report numbers) for each type.

(C) Enter one of the following codes:

(1) Code A—Fixed-Price Redetermination.

(2) Code J—Firm-Fixed-Price.

(3) Code K—Fixed-Price Economic Price Adjustment.

(4) Code L—Fixed-Price Incentive.

(5) Code M—Fixed-Price-Award-Fee.

(6) Code R—Cost-Plus-Award-Fee.

(7) Code S—Cost Contract.

(8) Code T—Cost-Sharing.

(9) Code U—Cost-Plus-Fixed Fee.

(10) Code V—Cost-Plus-Incentive-Fee.

(11) Code Y—Time-and-Materials.

(12) Code Z—Labor-Hour.

(vi) BLOCK C6, NUMBER OF OFFERORS SOLICITED.

(A) Leave Block C6 blank if—

(1) The original contract resulted from a solicitation issued before April 1, 1985 (i.e., before the effective date of the Competition in Contracting Act);

(2) Block B1B is coded B or C and Block B13A is coded 5; or

(3) Block B13A is coded 6.

(B) Otherwise, enter—

(1) Code 1—One. Enter code 1 if only one offeror was solicited; or

(2) Code 2—More than One. Enter code 2 if more than one offeror was solicited.

(vii) BLOCK C7, NUMBER OF OFFERS RECEIVED.

(A) Leave Block C7 blank if—

(1) The original contract resulted from a solicitation issued before April 1, 1985

(i.e., before the effective date of the Competition in Contracting Act); or

(2) Block B13A is coded 6, Order/Call Under Federal Schedule.

(B) Otherwise, enter the specific number of offers received (001–999).

(viii) BLOCK C8, SOLICITATION PROCEDURES.

(A) Leave Block C8 blank if—

(1) The original contract resulted from a solicitation issued before April 1, 1985 (i.e., before the effective date of the Competition in Contracting Act);

(2) The action is pursuant to simplified acquisition procedures (Block B13A is coded 9); or

(3) The action is an order or call under a Federal schedule (Block B13A is coded 6).

(B) Otherwise, enter one of the following codes:

(1) Code A—Full and Open Competition—Sealed Bid. Enter code A if the action resulted from an award pursuant to FAR 6.102(a).

(2) Code B—Full and Open Competition—Competitive Proposal. Enter code B if the action resulted from an award pursuant to FAR 6.102(b).

(3) Code C—Full and Open Competition—Combination. Enter code C if the action resulted from an award using a combination of competitive procedures (e.g., two-step sealed bidding) pursuant to FAR 6.102(c).

(4) Code D—Architect-Engineer. Enter code D if the action resulted from selection of sources for architect-engineer contracts pursuant to FAR 6.102(d)(1).

(5) Code E—Basic Research. Enter code E if the action resulted from competitive selection of basic research proposals pursuant to FAR 6.102(d)(2).

(6) Code F—Multiple Award Schedule. Enter code F if the action is an award of a multiple award schedule pursuant to FAR 6.102(d)(3) or an order against such a schedule.

(7) Code G—Alternative Sources. Enter code G if the action resulted from use of competitive procedures but excluded a particular source pursuant to FAR 6.202(a).

(8) Code K—Set-Aside. Enter code K if the action resulted from any—

(i) Set-aside for small business concerns (see FAR Subpart 19.5), including small business innovation research (SBIR) actions;

(ii) Set-aside for small disadvantaged business concerns;

(iii) Set-aside for HUBZone small business concerns (see FAR 19.1305);

(iv) Set-aside for very small business concerns (see FAR 19.904);

(v) Set-aside (including portions of broad agency announcements) for historically black colleges and universities or minority institutions (see 226.7003 and 235.016);

(vi) Competition among Section 8(a) firms under FAR 19.805 (report noncompetitive 8(a) awards as code N).

(9) Code M—Reserved.

(10) Code N—Other Full and Open Competition. Enter code N if the action resulted from use of other than full and open competition pursuant to FAR subpart 6.3. This includes awards to qualified nonprofit agencies employing people who are blind or severely disabled (see FAR subpart 8.7) or noncompetitive awards to the Small Business Administration under Section 8(a) of the Small Business Act (see FAR 6.302–5(b)).

(ix) BLOCK C9, AUTHORITY FOR OTHER THAN FULL AND OPEN COMPETITION.

(A) Leave Block C9 blank if the original contract resulted from a solicitation issued before April 1, 1985 (i.e., before the effective date of the Competition in Contracting Act).

(B) Enter one of the following codes if Block C8 is coded N. otherwise, leave Block C9 blank.

(1) Code 1A—Unique Source. Enter code 1A if the action was justified pursuant to FAR 6.302–1(b)(1).

(2) Code 1B—Follow-On Contract. Enter code 1B if the action was justified pursuant to FAR 6.302–1(a)(2)(ii) or (iii).

(3) Code 1C—Unsolicited Research Proposal. Enter code 1C if the action was justified pursuant to FAR 6.302–1(a)(2)(i).

(4) Code 1D—Patent/Data Rights. Enter code 1D if the action was justified pursuant to FAR 6.302–1(b)(2).

(5) Code 1E—Utilities. Enter code 1E if the action was justified pursuant to FAR 6.302–1(b)(3).

(6) Code 1F—Standardization. Enter code 1F if the action was justified pursuant to FAR 6.302–1(b)(4).

(7) Code 1G—Only One Source—Other. Enter code 1G if the action was justified pursuant to FAR 6.302–1 in a situation other than the examples cited in codes 1A through 1F.

(8) Code 1A—Urgency. Enter code 2A if the action was justified pursuant to FAR 6.302–2.

(9) Code 3A—Particular Sources. Enter code 3A if the action was justified pursuant to FAR 6.302–3(a)(2).

(10) Code 4A—International Agreement. Enter code 4A if the action was justified pursuant to FAR 6.302–4.

(11) Code 5A—Authorized by Statute. Enter code 5A if the action was justified pursuant to FAR 6.302–5(a)(2)(i).

(12) Code 5B—Authorizeds Resale. Enter code 5B if the action was justified pursuant to FAR 6.302–5(a)(2)(ii).

(13) Code 6A—National Security. Enter code 6A if the action was justified pursuant to FAR 6.302–6.

(14) Code 7A—Public Interest. Enter code 7A if the action was taken pursuant to FAR 6.302–7.

(x) BLOCK C10, SUBJECT TO LABOR STANDARDS STATUTES. Enter one of the following codes. When Block B13A is coded 6, leave Block C10 blank.

(A) Code A—Walsh-Healey Act. Enter code A when the contracting action is subject to the provisions of FAR subpart 22.6.

(B) Code C—Service Contract Act. Enter code C when the contracting action is subject to the provisions of the Service Contract Act (see FAR part 37).

(C) Code D—Davis-Bacon Act. Enter code D when the contracting action is subject to the Davis-Bacon Act (see FAR 22.403–1).

(D) Code Z—Not Applicable. Enter code Z when codes A, C, and D do not apply.

(xi) BLOCK C11, COST OR PRICING DATA. Enter one of the following codes when Block B1B is coded A. Otherwise, leave Block C11 blank.

(A) Code Y—Yes—Obtained. Enter code Y when cost or pricing data were obtained (see FAR 15.403–4) and certified in accordance with FAR 15.406–2.

(B) *Code N—No—Not Obtained.* Enter code N when neither code Y nor code W applies.

(C) *Code W—Not Obtained—Waived.* Enter code W when cost or pricing data were not obtained because the requirement was waived (see FAR 15.403–1(c) (4)).

(xii) BLOCK C12, CONTRACT FINANCING. Enter one of the following codes identifying whether or not progress payments (PP), advance payments (AP), or other financing methods were used.

(A) *Code A—FAR 52.232–16.* Enter code A if the contract contains the clause at FAR 52.232–16, Progress payments.

(B) *Code B—Reserved.*

(C) *Code C—Percentage of Completion PP.* Enter code C if the contract provides for progress payments based on percentage or stage of completion, which is only permitted on contracts for construction, for shipbuilding, or for ship conversion, alteration, or repair (see 232.102(e)(2)).

(D) *Code D—Unusual PP or AP.* Enter code D if the contract provides unusual progress payments or advance payments (see FAR subpart 32.4 and 32.501–2).

(E) *Code E—Commercial Financing.* Enter code E if the contract provides for commercial financing payments (see FAR subpart 32.2)

(F) *Code F—Performance-Based Financing.* Enter code F if the contract provides for performance-based financing payments (see FAR subpart 32.10).

(G) *Code Z—Not Applicable.* Enter code Z when codes A through F do not apply.

(xiii) BLOCK C13, FOREIGN TRADE DATA.

(A) The term ''United States (U.S.),'' as used in Block C13, excludes the Trust Territory of Palau (see 204. 670–1 for definition of United States and outlying areas).

(B) BLOCK C13A, PLACE OF MANUFACTURE. Complete Block C13A only if the contracting action is for a foreign end product or a service provided by a foreign concern. Otherwise, leave Block C13A blank.

(1) Code A—U.S. Enter code A if the contracting action is for—

(i) A foreign end product that is manufactured in the United States but still determined to be foreign because 50 percent or more of the cost of its components is not mined, produced, or manufactured inside the United States or inside qualifying countries; or

(ii) Services performed in the United States by a foreign concern.

(2) Code B—Foreign. Enter code B if the contracting action is for—

(i) Any other foreign end product; or

(ii) Services performed outside the United States by a foreign concern.

(C) BLOCK C13B, COUNTRY OF ORIGIN CODE.

(1) Complete Block C13B only if Block C13A is coded A or B. Otherwise, leave Block C13B blank.

(2) Enter the code from FIPS PUB 10, Countries, Dependencies, Areas of Special Sovereignty, and Their Principal Administrative Divisions, that identifies the country where the foreign product is coming from or where the foreign company providing the services is located. If more than one foreign country is involved, enter the code of the foreign country with the largest dollar value of work under the contract.

(xiv) BLOCK C14, COMMERCIAL ITEMS. Enter one of the following codes:

(A) *Code Y—Yes.* Enter code Y if the contract contains the clause at FAR 52.212–4, Contract Terms and Conditions-Commercial Items.

(B) *Code N—No.* Enter code N if code Y does not apply.

(d) *Part D of the DD Form 350.*

(1) Do NOT complete part D if the contracting action is with a government agency, i.e., Block B5B is coded Y.

(2) If the action is an order or call under a Federal schedule, complete only Blocks D1 and D6.

(3) Use the codes in Blocks B13A and B13D to determine whether the codes in Part D will describe the contracting action being reported or the original contract.

(i) Code Part D to describe the contracting action being reported when—

(A) Block B13A is coded, 1, 3, 4, or 9 and Block B13D is coded A or is blank; or

(B) Block B5B is coded N, Block B13A is coded, 8, and Block B13D is coded A or is blank.

(ii) Otherwise, code Part D to describe the original contract. If there are no codes for the original contract because a DD Form 350 was not required at the time, the original action is no longer available, the definition of the original code has changed, or a data element has been added to the system after the original contract report, use codes that best describe the original contracting action.

(4) Determine the status of the concern (e.g., size and ownership) by referring to FAR part 19 and DFARS part 219. For an order or call under a Federal schedule, refer to the schedule or comply with departmental instructions.

(5) Complete Part D blocks as follows:

(i) BLOCK D1, TYPE OF CONTRACTOR.

(A) BLOCK D1A, TYPE OF ENTITY. Enter one of the following codes:

(1) Code A—Small Disadvantaged Business Performing in U.S. Enter code A if the contractor is a small disadvantaged business concern as defined in 219.001 and the place of performance is within the United States and outlying areas.

(2) Code B—Other Small Business Performing in U.S. Enter code B if the contractor is a small business concern as defined in FAR 19.001, other than a small disadvantaged business concern, and the place of performance is within the United States and outlying areas.

(3) Code C—Large Business Performing in U.S. Enter code C if the contractor is a domestic large business concern and the place of performance is within the United States and outlying areas.

(4) Code D—JWOD Participating Nonprofit Agency. Enter code D if the contractor is a qualified nonprofit agency employing people who are blind or severely disabled (see FAR 8.701) and the place of performance is within the United States and outlying areas.

(5) Code F—Hospital. Enter code F if the contractor is a hospital and the place of performance is within the United States and outlying areas.

(6) Code L—Foreign Concern/Entity. Enter code L if the contractor is a foreign concern, the Canadian Commercial Corporation, or a non-U.S.-chartered nonprofit institution.

(7) Code M—Domestic Firm Performing Outside U.S. Enter code M if the contractor is a domestic concern or a domestic nonprofit institution and the place of performance is outside the United States and outlying areas.

(8) Code U—Historically Black College or University or Minority Institution (HBCU/MI). Enter code U if the contractor is an HBCU/MI as defined at 252.226–7000 and the place of performance is within the United States and outlying areas.

(9) Code V—Other Educational. Enter code V if the contractor is an educational institution that does not qualify as an HBCU/MI and the place of performance is within the United States and outlying areas.

(10) Code Z—Other Nonprofit. Enter code Z if the contractor is a nonprofit institution (defined in FAR 31.701) that does not meet any of the criteria in codes D, F, U, or V and the place of performance is within the United States and outlying areas.

(B) BLOCK D1B, HUBZONE REPRESENTATION. Enter one of the following codes when Block D1A is coded A or B. Otherwise, leave Block D1B blank.

(1) Code Y—Yes. Enter code Y if the contractor represented that it is a HUBZone small business concern (see FAR 19.1303).

(2) Code N—No. Enter code N if code Y does not apply.

(ii) BLOCK D2, REASON NOT AWARDED TO SMALL DISADVANTAGED BUSINESS (SDB). Enter one of the following codes when Block D1A is coded B or C. Otherwise, leave Block D2 blank.

(A) *Code A—No Known SDB Source.*

(B) *Code B—SDB Not Solicited.* Enter code B when there was a known SDB source, but it was not solicited.

(C) *Code C—SDB Solicited/No Offer.* Enter code C when an SDB was solicited but it did not submit an offer, or its offer was not sufficient to cover the total quantity requirement so it received a separate award for the quantity offered.

(D) *Code D—SDB Solicited/Offer Not Low.* Enter code D when an SDB offer was not the low offer or an SDB was not willing to accept award of a partial small business set-aside portion of an action at the price offered.

(E) *Code Z—Other Reason.* Enter code Z when an SDB did not receive the award for any other reason or when Block B1B is coded B or C and Block B13A is coded 5.

(iii) BLOCK D3, REASON NOT AWARDED TO SMALL BUSINESS (SB). Enter one of the following codes when Block D1A is coded C. Otherwise, leave D3 blank. (The term ''small business'' includes all categories of small businesses.)

(A) *Code A—No Known SB Source.*

(B) *Code B—SB Not Solicited.* Enter code B when there was a known small business source, but it was not solicited.

(C) *Code C—SB Solicited/No Offer.* Enter code C when a small business concern was solicited but it did not submit an offer, or its offer was not sufficient to cover the total quantity requirement so it received a separate award for the quantity offered.

(D) *Code D—SB Solicited/Offer Not Low.* Enter code D when a small business offer was not the low or most advantageous offer or a small business concern was not willing to accept award of a set-aside portion of an action at the price offered by the Government.

(E) *Code Z—Other Reason.* Enter code Z when a small business did not receive the award for any other reason or when Block B1B is coded B or C and Block B13A is coded 5.

(iv) BLOCK D4, PREFERENCE PROGRAM.

(A) BLOCK D4A, TYPE OF SB SET-ASIDE. Enter one of the following codes:

(1) Code A—None. Enter code A if there was no small business set-aside (see FAR 19.502). Note that set-asides for historically black colleges and universities and minority institutions (HBCUs/MIs) are not small business set-asides. Use code A for HBCU/MI set-asides and complete Block D4C.

(2) Code B—Total SB Set-Aside. Enter code B if the action was a total set-aside for small business (see FAR 19.502–2), including actions reserved exclusively for small business concerns pursuant to FAR 13.003(b)(1), or if the action resulted from the Small Business Innovation Research Program.

(3) Code C—Partial SB Set-Aside. Enter code C if the action was a partial set-aside for small business (see FAR 19.502–3).

(4) Code E—Total SDB Set-Aside. Enter code E if the action was a total set-aside for small disadvantaged businesses.

(5) Code F—Very Small Business Set-Aside. Enter code F if the action was a set-aside for very small businesses (see FAR subpart 19.9).

(6) Code Y—Emerging Small Business Set-Aside. Enter code Y if the action was an emerging small business set-aside within a designated industry group under the Small Business Competitiveness Demonstration Program (see FAR subpart 19.10).

(B) BLOCK D4B, TYPE OF SDB SET-ASIDE/SDB PREFERENCE. Enter one of the following codes, even if Block D4A is coded E:

(1) Code A—None. Enter code A if no SDB preference was given or award was not to an SDB.

(2) Code B—Section 8(a). Enter code B if the contract was awarded to—

(i) The Small Business Administration under Section 8(a) of the Small Business Act (see FAR subpart 19.8); or

(ii) An 8(a) contractor under the direct award procedures at 219.811.

(3) Code C—Total SDB Set-Aside. Enter code C if the action was an SDB set-aside and award was to an SDB.

(4) Code D—SDB Price Evaluation Adjustment—Unrestricted. Enter code D if the action was unrestricted but an SDB received an award as a result of a price evaluation adjustment (see FAR subpart 19.11).

(5) Code E—SDB Preferential Consideration—Partial SB Set-Aside. Enter code E if the action was a partial set-aside for small business and preferential consideration resulted in an award to an SDB.

(C) BLOCK D4C, HBCU/MI SET-ASIDE. Enter one of the following codes:

(1) Code A—None. Enter code A if the action was not set aside for HBCUs or MIs.

(2) Code B—HBCU or MI—Total Set-Aside. Enter code B if the action was a total set-aside for HBCUs and MIs (see 226.7003).

(3) Code C—HBCU or MI—Partial Set-Aside. Enter code C if the action was a partial set-aside for HBCUs or MIs under a broad agency announcement (see 235.016).

(D) BLOCK D4D. TYPE OF HUBZONE PREFERENCE. Enter one of the following codes:

(1) Code A—None. Enter code A if no preference was given to HUBZone small business concerns.

(2) Code B—Set-Aside. Enter code B if the contractor received the award as a result of a HUBZone set-aside (see FAR 19.1305).

(3) Code C—Price Evaluation Preference. Enter code C if the contractor received the award as a result of a HUBZone price evaluation preference (see FAR 19.1307).

(4) Code D—Sole Source Award. Enter Code D if the contractor received the award as a result of a HUBZone sole source action (see FAR 19.1306).

(E) BLOCK D4E, PREMIUM PERCENT.

(1) Complete Block D4E if Block B1B is coded A and—

(i) Block D4B is coded C, D, or E;

(ii) Block D4C is coded B or C; or

(iii) Block D4D is coded C.

(2) Otherwise, leave Block D4E blank.

(3) Calculate the premium percentage per 219.202–5 and enter it as a three-digit number rounded to the nearest tenth, e.g., enter 7.55% as 076. If no premium was paid, enter three zeros (000).

(v) BLOCK D5, ETHNIC GROUP.

(A) Complete Block D5 if the action is with an SDB. Otherwise, leave Block D5 blank.

(B) Enter the code from the following list that corresponds to the ethnic group marked by the contractor in the solicitation provision at FAR 52.219–1, Small Business Program Representations, or FAR 52.212–3(c).

(1) Code A—Asian-Indian American.

(2) Code B—Asian-Pacific American.

(3) Code C—Black American.

(4) Code D—Hispanic American.

(5) Code E—Native American.

(6) Code F—Other SDB Certified/ Determined by SBA.

(7) Code Z—No Representation.

(vi) BLOCK D6, WOMEN-OWNED BUSINESS. Enter one of the following codes:

(A) *Code Y—Yes.* Enter code Y if—

(1) The contractor's response to FAR 52.204–5, 52.212–3(c), or 52.219–1(b) indicates that it is a women-owned business; or

(2) Block B13A is coded 6 and the Federal schedule indicates that the contractor is a women-owned business.

(B) *Code N—No.* Enter code N if—

(1) The contractor's response to FAR 52.204–5, 52.212–3(c), or 52.219–1(b) indicates that it is not a women-owned business; or

(2) Block B13A is coded 6 and the Federal schedule indicates that the contractor is not a women-owned business.

(C) *Code U—Uncertified.* Enter code U if the information is not available because the contractor did not complete the representation under FAR 52.204–5, 52.212–3(c), or 52.19–1(b).

(vii) BLOCK D7, SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM. Enter one of the following codes. When Block B1B is coded B or C and Block B13A is coded 5, leave Block D7 blank.

(A) *Code A—Not a SBIR Program Phase I/II/III.* Enter code A if the action is not in support of a Phase I, II, or III SBIR Program.

(B) *Code B—SBIR Program Phase I Action.* Enter code B if the action is related to a Phase I contract in support of the SBIR Program.

(C) *Code C—SBIR Program Phase II Action.* Enter code C if the action is

related to a Phase II contract in support of the SBIR Program.

(D) *Code D—SBIR Program Phase III Action.* Enter D if the action is related to a Phase III contract in support of the SBIR Program.

(viii) BLOCK D8, SUBCONTRACTING PLAN—SB, SDB, OR HBCU/MI. Enter one of the following codes:

(A) *Code A—Plan Not Included—No Subcontracting Possibilities.* Enter code A if a subcontracting plan was not included in the contract because subcontracting possibilities do not exist (see FAR 19.705–2(c)).

(B) *Code B—Plan Not Required.* Enter code B if no subcontracting plan was required (e.g., because the action did not meet the dollar thresholds in FAR 19.702(a)).

(C) *Code C—Plan Required, Incentive Not Included.* Enter code C if the action includes a subcontracting plan, but does not include additional incentives (see FAR 19.708(c)).

(D) *Code D—Plan Required, Incentive Included.* Enter code D if the action includes a subcontracting plan and also includes additional incentives (see FAR 19.708(c) and 219.708(c)).

(ix) BLOCK D9, SMALL BUSINESS COMPETITIVENESS DEMONSTRATION PROGRAM. Enter one of the following codes. When Block B13A is coded 5 or Block B13D is coded B, C, D, E, F, or G and the original action was awarded before the program began, enter code N in Block D9. When Block B1B is coded B or C and Block B13A is coded 5, enter code N in Block D9.

(A) *Code Y—Yes.* Enter code Y if this is an action with a U.S. business concern, in either the four designated industry groups or the ten targeted industry categories under the Small Business Competitiveness Demonstration Program (see FAR subpart 19.10 and DFARS subpart 219.10), where the principal place of performance is in the United States or outlying areas.

(B) *Code N—No.* Enter code N if code Y does not apply.

(x) BLOCK D10, SIZE OF SMALL BUSINESS.

(A) Complete Block D10 only when Block D9 is coded Y and the contractor is a small business (Block D1 is coded A or B). Otherwise, leave Block D10 blank.

(B) Enter one of the following codes for the size of the business (number of employees or average annual gross revenue) as represented by the contractor in the solicitation provision at FAR 52.219–19, Small Business Concern Representation for the Small Business Competitiveness Demonstration Program:

(1) Code A—50 or fewer employees.
(2) Code B—51–100 employees.
(3) Code C—101–250 employees.
(4) Code D—251–500 employees.
(5) Code E—501–750 employees.
(6) Code F—751–1,000 employees.
(7) Code G—Over 1,000 employees.
(8) Code M—$1,000,000 or less.
(9) Code N—$1,000,001–$2,000,000.
(10) Code P—$2,000,001–$3,500,000.
(11) Code R—$3,500,001–$5,000,000.
(12) Code S—$5,000,001–$10,000,000.
(13) Code T—$10,000,001–$17,000,000.
(14) Code U—Over 17,000,000.

(xi) BLOCK D11, EMERGING SMALL BUSINESS.

(A) Complete this block only if Block D9 is coded Y and the contracting action is in one of the four designated industry groups, not one of the targeted industry categories. Otherwise, leave Block D11 blank.

(B) Enter one of the following codes:

(1) Code Y—Yes. Ener code Y if the contractor represents in the provision at FAR 52.219–19, Small Business Concern Representation for the Small Business Competitiveness Demonstration Program, that it is an emerging small business concern.

(2) Code N—No. Enter code N if code Y does not apply.

(e) *Part E of the DD Form 350.* Part E gathers data on specialized items that may not become permanent reporting elements.

(1) BLOCK E1, CONTINGENCY, HUMANITARIAN, OR PEACEKEEPING OPERATION.

(i) Enter code Y in Block E1 if the contracting action exceeds $200,000 and is in support of—

(A) A contingency operation as defined in 10 U.S.C. 101(a)(13); or

(B) A humanitarian or peacekeeping operation as defined in 10 U.S.C. 2302(7).

(ii) Otherwise, leave Block E1 blank.

(2) BLOCK E2, COST ACCOUNTING STANDARDS CLAUSE. Enter code Y in Block E2 if the contract includes a Cost Accounting Standards clause (see FAR Part 30). Otherwise, leave Block E2 blank.

(3) BLOCK E3–BLOCK E8. Reserved.

(f) *Part F of the DD Form 350.* Part F identifies the reporting official.

(1) BLOCK F1, NAME OF CONTRACTING OFFICER OR REPRESENTATIVE. Enter the name (Last, First, Middle Initial) of the contracting officer or representative.

(2) BLOCK F2, SIGNATURE. The person identified in Block F1 must sign.

(3) BLOCK F3, TELEPHONE NUMBER. Enter the telephone number (with area code) for the individual in Block F1. Installations with Defense Switched Network (NSN) must enter the DSN number.

(4) BLOCK F4, DATE. Enter the date that the DD Form 350 Report is submitted. Enter four digits for the year, two digits for the month, and two digits for the day. Use 01 through 12 for January through December. For example, enter January 2, 2003, as 20030102.

6. Section 253.204–71 is amended by revising paragraph (g) to read as follows:

253.204–71 DD Form 1057, Monthly Contracting Summary of Actions $25,000 or Less.

* * * * *

(g) *Section, E, Selected Socioeconomic Statistics.*

(1) BLOCK E1, SMALL BUSINESS (SB) SET-ASIDE.

(i) Enter the total number and dollar value of contracting actions that were small business set-aside actions, including awards to SDBs reported in Blocks E2c and E2d. Do not include orders under Federal schedules that are reported in Block E3 or E5.

(ii) If the action is an emerging small business set-aside (see FAR 19.1006(c)), use the most appropriate sub-block.

(iii) Enter the subtotals for the number and total dollar value of actions for—

(A) Block E1a, SB Set-Aside Using Simplified Acquisition procedures. Enter actions pursuant to FAR 13.003(b)(1).

(B) Block E1b, SB Set-Aside. Enter actions pursuant to FAR 19.502.

(2) BLOCK 32, SMALL DISADVANTAGED BUSINESS (SDB) ACTIONS.

(i) Enter the total number and dollar value of actions that were SDB actions. Do not include orders under Federal schedules that are reported in Block E3 or E5.

(ii) Enter the subtotals for the number and dollar value for—

(A) Block E2a, Through SBA—Section 8(a). Enter actions with the Small Business Administration pursuant to Section 8(a) of the Small Business Act (see FAR subpart 19.8) or under the 8(a) direct award procedures at 219.811.

(B) Block E2b, SDB Set-Aside/SDB Preference/Evaluation Adjustment. Enter actions resulting from—

(1) A set-aside for SDB concerns;

(2) Application of an SDB price preference or evaluation adjustment (see FAR subpart 19.11); or

(3) SDB preferential consideration.

(C) Block E2c, SB Set-Aside Using Simplified Acquisition Procedures. Enter actions pursuant to FAR 13.003(b)(1) when award is to an SDB, but a preference or evaluation adjustment was not applied.

(D) Block E2d, SB Set-Aside. Enter Actions under FAR 19.502 when award is to an SDB, but a preference or evaluation adjustment was not applied nor was preferential consideration given.

(E) Block E2e, Other. Enter awards to SDB concerns when award is to an SDB not reported in Blocks E2a through E2d.

(3) BLOCK E3, SDB FEDERAL SCHEDULE ORDERS. Enter the total number and dollar value of contracting actions that were orders under Federal schedules with SDBs.

(4) BLOCK E4, WOMEN-OWNED SMALL BUSINESS. Enter the total number and dollar value of contracting actions with women-owned small businesses (see FAR 19.304(a)). Do not include orders under Federal schedules that are reported in Block E5.

(5) BLOCK E5, WOMEN-OWNED SMALL BUSINESS FEDERAL SCHEDULE ORDERS. Enter the total number and dollar value of contracting actions that were orders under Federal schedules with women-owned small businesses.

(6) BLOCK E6, HBCU/MI. Enter the total number and dollar value of contracting actions with HBCU/MIs pursuant to subpart 226.70.

(7) BLOCK E7, JWOD PARTICIPATING NONPROFIT AGENCIES. Enter the total number and dollar value of contracting actions with qualified nonprofit agencies employing people who are blind or severely disabled for supplies or services from the Procurement List pursuant to FAR subpart 8.7.

(8) BLOCK E8, EXEMPT FROM SMALL BUSINESS ACT REQUIREMENTS. Enter the total number and dollar value of contacting actions exempt from the set-aside requirements of the Small Business Act (see FAR 19.502–1).

(9) BLOCK E9, HUBZONE.

(i) Enter the total number and dollar value of contracting actions that were awarded to HUBZone small business concerns in each of the following categories:

(A) Block E9a, HUBZone Set-Aside.

(B) Block E9b, HUBZone Price Evaluation Preference.

(C) Block E9c, HUBZone Sole Source.

(D) Block E9d, HUBZone Concern-Other. Use this category when the award is to a HUBZone small business concern and Blocks E9a, E9b, and E9c do not apply.

(ii) Do not include orders under Federal schedules that are reported in Block E3 or E5. Do not total the values for Block E9.

* * * * *

[FR Doc. 99–21418 Filed 8–18–99; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

49 CFR Part 396

Inspection, Repair, and Maintenance

CFR Correction

In Title 49 of the Code of Federal Regulations, parts 200 to 399, revised as of Oct. 1, 1998, on page 900, § 396.19 is corrected by reinstating the correct text of paragraph (b) to read as follows:

§ 396.19 Inspector qualifications.

* * * * *

(b) Evidence of that individual's qualifications under this section shall be retained by the motor carrier for the period during which that individual is performing annual motor vehicle inpspections for the motor carrier, and for one year thereafter. However, motor carriers do not have to maintain documentation of inspector qualifications for those inspections performed either as part of a State periodic inspection program or at the roadside as part of a random roadside inspection program.

[FR Doc. 99–55525 Filed 8–18–99; 8:45 am]

BILLING CODE 1505–01–D

Proposed Rules

Federal Register
Vol. 64, No. 160
Thursday, August 19, 1999

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

Agricultural Marketing Service

7 CFR Part 984

[Docket No. FV99–984–2 PR]

Walnuts Grown in California; Reporting Walnuts Grown Outside of the United States and Received by California Handlers

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule invites comments on revising the administrative rules and regulations of the Federal marketing order for California walnuts (order) to require handlers to report receipts of walnuts grown outside of the United States. This proposal also announces the Agricultural Marketing Service's (AMS) intention to request a revision to the currently approved information collection requirements issued under the order. The order regulates the handling of walnuts grown in California and is administered locally by the Walnut Marketing Board (Board). Requiring handlers to report to the Board receipts of walnuts grown outside of the United States would allow the Board to have better information on the total available supply of walnuts within California, which includes both California and foreign product. This would facilitate program administration.

DATES: Comments must be received by October 18, 1999.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Fruit and Vegetable Programs, AMS, USDA, P.O. Box 96456, room 2525–S, Washington, DC 20090–6456; Fax: (202) 720–5698; or E-mail: moabdocket.clerk@usda.gov. Comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Maureen T. Pello, Marketing Specialist, California Marketing Field Office, Fruit and Vegetable Programs, AMS, USDA, 2202 Monterey Street, Suite 102B, Fresno, California 93721; telephone: (559) 487–5901; Fax: (559) 487–5906; or George Kelhart, Technical Advisor, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, P.O. Box 96456, room 2525–S, Washington, DC 20090–6456; telephone: (202) 720–2491, Fax: (202) 720–5698. Small businesses may request information on complying with this regulation, or obtain a guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, P.O. Box 96456, room 2525–S, Washington, DC 20090–6456; telephone (202) 720–2491, Fax: (202) 720–5698, or E-mail: Jay.Guerber@usda.gov. You may view the marketing agreement and order small business compliance guide at the following web site: http://www.ams.usda.gov/fv/moab.html.

SUPPLEMENTARY INFORMATION: This proposal rule is issued under Marketing Agreement and Order No. 984, both as amended (7 CFR part 984), regulating the handling of walnuts grown in California, hereinafter referred to as the ''order.'' The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

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

This proposal has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This proposal will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

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

This proposed rule invites comments on revising the order's administrative rules and regulations to require handlers to report to the Board receipts of walnuts grown outside of the United States. This would allow the Board to have better information on the total available supply of walnuts within California, which includes both California and foreign product, which would facilitate program administration. This action was unanimously recommended by the Board at a meeting on September 11, 1998.

Section 984.76 of the order provides authority for the Board, with the approval of the Secretary, to require handlers to furnish reports and information to the Board as needed to enable the Board to perform its duties under the order. The Board meets during the season to make decisions on various programs authorized under the order. These programs include quality control (minimum grade and size requirements for both inshell and shelled walnuts placed into channels of commerce), volume regulation, and projects regarding production research, and marketing research and development.

The Board would like to have better information on the total supply of walnuts within California, which includes both California and foreign product. The Board would use this information in its marketing policy deliberations each fall when it reviews the crop estimate, handler carryover, and other factors to determine whether volume regulation would be appropriate. In addition, the Board has some concerns that, particularly in short crop years when handlers may import more walnuts to meet customer demands, imported walnuts could be

included in handler inventory reports of California walnuts. Accurate information regarding the supply of walnuts within California is needed by the Board in its administration of the order.

According to the National Agricultural Statistics Service, the 10-year average annual production of California walnuts is 235,000 inshell tons. Bureau of Census data indicates that the 10-year average annual import figure for walnuts is 1,036.5 shelled tons. However, during short crop years in California such as the 1992–93 (203,000 inshell tons) and 1996–97 (208,000 inshell tons) seasons, imports increased to 8,046 and 5,806 shelled tons, respectively.

Thus, the Board recommended that handlers be required to report to the Board receipts of walnuts grown outside of the United States. This report, WMB Form No. 7, would be submitted to the Board four times per year as follows: On or before November 5 for such walnuts received during the period August 1 to October 31; on or before February 5 for such walnuts received during the period November 1 to January 31; on or before May 5 for such walnuts received during the period February 1 to April 30; and on or before August 5 for such walnuts received during the period May 1 to July 31. The report would include the quantity of such walnuts received, country of origin, and whether such walnuts were inshell or shelled.

The Board also recommended that, with each report, the handler submit a copy of a product tag issued by the Dried Fruit Association of California (DFA) for compliance purposes. The DFA is a private agency designated under the marketing order to provide inspection services for handlers to ensure that California walnuts meet minimum grade and size requirements in effect under the order. The product tag would indicate the name of the person from whom the walnuts were received, the date the walnuts were received by the handler, the number of containers and U.S. Custom's Service entry number, whether the product is inshell or shelled, the quantity of walnuts, country of origin, the name of the DFA inspector who issued the tag, and the date such tag was issued. The Board believes product tags are necessary to verify handler receipt reports for imported walnuts. Accordingly, a new § 984.476 is proposed to be added to the orders' administrative rules and regulations.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the AMS has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 5,000 producers of walnuts in the production area and approximately 50 handlers subject to regulation under the order. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $5,000,000. The majority of producers of California walnuts may be classified as small entities.

During the 1997–98 season, as a percentage, 33 percent of the handlers shipped over 2.4 million kernelweight pounds of walnuts, and 67 percent of the handlers shipped under 2.4 million kernelweight pounds of walnuts. Based on an average price of $2.10 per kernelweight pound at the point of first sale, the majority of handlers of California walnuts may be classified as small entities.

This rule would add a new § 984.476 to the order's administrative rules and regulations which would require handlers to report to the Board receipts of walnuts grown outside of the United States. This would allow the Board to have better information on the total available supply of walnuts, including California and foreign product, which would facilitate program administration. Authority for requiring handlers to submit this information to the Board is provided in § 984.76 of the order.

Regarding the impact of the proposed action on affected entities, this rule should impose minimal additional costs. The Board estimates that about six handlers have imported walnuts over the past few years. Such handlers would be required to submit an additional report to the Board four times per year along with tags issued by the DFA verifying receipts of foreign product. The DFA currently provides inspection services for all handlers of California walnuts and would be available at no additional cost to issue product tags to handlers receiving imports. Handlers would then submit these tags to the Board for verification purposes.

An alternative to the proposed action would be to not collect information from handlers on receipts of imported walnuts. However, as previously mentioned, the Board would like to have better information on the total available supply of walnuts within California, which includes both California and foreign product. The only way this information can be obtained by the Board is to collect it from handlers. This information would facilitate program administration by improving the Board's base of information from which to make decisions.

The Board also recommended that a system be established for monitoring walnuts grown outside of the United States that are received by California handlers. Under the proposed monitoring system, DFA inspectors would check whether or not foreign product had been inspected and met the requirements of section 8e of the Act. Under section 8e, whenever certain specified commodities are regulated under a Federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality, and maturity requirements as those in effect for the domestic commodity. Walnuts are included under section 8e, and thus importers of walnuts are required to have such walnuts inspected. However, it is the USDA's responsibility to ensure that imported walnuts meet the requirements of section 8e. Thus, we are not proceeding with this recommendation.

Finally, the Board considered whether it would be useful to collect information on walnuts grown outside of California, but within the United States. However, Board members agreed that the amount of such walnuts was so small, it was not worth requiring handlers to report such information.

This action would impose some additional reporting and recordkeeping burden on handlers that receive walnuts grown outside of the United States. It is estimated that six handlers may import walnuts during the season. Such handlers would be required to submit a receipt report to the Board four times per year. It is estimated that it would take such handlers 5 minutes to complete each report. Thus, the additional annual burden should total no more than 2 hours for the industry. The information would be collected on WMB Form No. 7. That form is being submitted to the Office of Management and Budget (OMB) for approval under OMB Control No. 0581–0178. As with other similar marketing order programs,

reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

The Department has identified one relevant Federal rule regarding requirements for walnuts grown outside of the United States. As previously stated, walnuts are included under section 8e. Thus, importers of walnuts are required to have such walnuts inspected by the USDA's inspection service. Importers whose walnuts meet section 8e requirements do not have to submit any paperwork to the USDA. However, importers whose walnuts fail section 8e requirements, or whose walnuts are exempt from section 8e because such walnuts are so immature that they cannot be used for drying and sale as dried walnuts (green walnuts), or are being sent to designated outlets (animal feed, processing, or charity) have to submit paperwork to the USDA. However, only a small amount of information requested by the USDA in these instances or by the Board through this rule, would be duplicative.

In addition, the Board's meeting on September 11, 1998, where this action was deliberated was a public meeting widely publicized throughout the walnut industry. This issue was also deliberated at an earlier Board meeting on February 2, 1998, and at a Grades and Standards Subcommittee meeting on June 5, 1998. All interested persons were invited to attend these meetings and participate in the industry's deliberations. Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the AMS announces its intention to request a revision to a currently approved information collection for vegetable and specialty crop marketing orders, which includes the Federal marketing order for California walnuts.

Title: Vegetable and Specialty Crop Marketing Orders.

OMB Number: 0581–0178.

Expiration Date of Approval: July 31, 2000.

Type of Request: Intent to revise a currently approved information collection.

Abstract: The information collection requirements in this request are essential to carry out the intent of the Act, to provide the respondents the type of service they request, and to administer the California walnut marketing order program, which has been operating since 1948.

On September 11, 1998, the Board unanimously recommended revising the order's administrative rules and regulations to require handlers to report to the Board receipts of walnuts grown outside of the United States. This information would be reported on WMB Form No. 7. This notice concerns this report, in addition to the accompanying regulation previously discussed regarding requiring this report be submitted by handlers to the Board.

The Board would like to have better information on the total supply of walnuts available within California, which includes both California and foreign product. The Board would use this information in its marketing policy deliberations each fall when it reviews the crop estimate, handler carryover, and other factors to determine whether volume regulation would be appropriate. In addition, the Board has some concerns that, particularly in short crop years when handlers may import more walnuts to meet customer demands, imported walnuts could be included in handler inventory reports of California walnuts. Accurate information regarding the supply of walnuts within California is needed by the Board in its administration of the order.

The information collected is used only by authorized representatives of the USDA, including AMS, Fruit and Vegetable Programs regional and headquarter's staff, and authorized employees of the Board. Authorized Board employees and the industry are the primary users of the information and AMS is the secondary user.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 5 minutes per response.

Respondents: California walnut handlers who receive walnuts grown outside of the United States.

Estimated Number of Respondents: 6.

Estimated Number of Responses per Respondent: 4.

Estimated Total Annual Burden on Respondents: 2 hours.

Comments: Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) 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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments should reference OMB No. 0581–0178 and the Vegetable and Specialty Crop Marketing Orders, and be sent to the USDA in care of the Docket Clerk at the address above. All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

A 60-day comment period is provided to allow interested persons to respond to this proposal.

List of Subjects in 7 CFR Part 984

Marketing agreements, Nuts, Reporting and recordkeeping requirements, Walnuts.

For the reasons set forth in the preamble, 7 CFR part 984 is proposed to be amended as follows:

PART 984—WALNUTS GROWN IN CALIFORNIA

1. The authority citation for 7 CFR part 984 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. A new § 984.476 is added to read as follows:

§ 984.476 Report of walnut receipts from outside of the United States.

Each handler who receives walnuts from outside of the United States shall file with the Board, on WMB Form No. 7, a report of the receipt of such walnuts. The report shall be filed as follows: On or before November 5 for such walnuts received during the period August 1 to October 31; on or before February 5 for such walnuts received during the period November 1 to January 31; on or before May 5 for such walnuts received during the period February 1 to April 30; and on or before August 5 for such walnuts received during the period May 1 to July 31. The report shall include the quantity of such walnuts received, the country of origin for such walnuts, and whether such walnuts are inshell or shelled. With each report, the handler shall submit a copy of a product tag issued by a DFA of California inspector for each receipt of such walnuts that includes the name of the person from whom such walnuts were received, the date such walnuts were received by the handler, the number of containers and the U.S. Custom's Service entry number,

whether such walnuts are inshell or shelled, the quantity of such walnuts received, the country of origin for such walnuts, the name of the DFA of California inspector who issued the product tag, and the date such tag was issued.

Dated: August 17, 1999.

Robert C. Keeney,

Deputy Administrator, Fruit and Vegetable Programs.

[FR Doc. 99–21666 Filed 8–18–99; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–NM–206–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Proposed rule; withdrawal.

SUMMARY: This action withdraws a notice of proposed rulemaking (NPRM) that proposed a new airworthiness directive (AD), applicable to certain Boeing Model 767 series airplanes. That action would have required replacement of the existing retaining bolt of the attendant seat lap belt with a new bolt and a washer. Since the issuance of the NPRM, the Federal Aviation Administration (FAA) has received new data indicating that the proposed action has already been accomplished on all affected airplanes. Accordingly, the proposed rule is withdrawn.

FOR FURTHER INFORMATION CONTACT: Meghan Gordon, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2207; fax (425) 227–1181.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add a new airworthiness directive (AD), applicable to certain Boeing Model 767 series airplanes, was published in the **Federal Register** as a Notice of Proposed Rulemaking (NPRM) on June 6, 1997 (62 FR 31020). The proposed rule would have required replacement of the existing retaining bolt of the attendant seat lap belt with a new bolt and a washer. That action was prompted by reports indicating that, due to a missing washer, the belt end fittings of the double flight attendant seats can become loose. The proposed actions were intended to ensure that a washer between the bolt head and bushing is installed. A missing washer could allow movement of the belt end fittings, which can cause the restraint belts to release and, consequently, result in injury to the flight attendants.

Actions Since Issuance of the NPRM

Since the issuance of that NPRM, the FAA has received a comment from the airplane manufacturer indicating that the replacement of the existing retaining bolt of the attendant seat lap belt with a new bolt and a washer, in accordance with Boeing Service Bulletin 767–25–0217, dated January 13, 1994, has been accomplished on all affected airplanes. Though the manufacturer did not provide documentation to support its statement, the FAA also has received substantiating documentation from each affected operator that the service bulletin has been incorporated on its fleet of airplanes. In the case of one operator, the FAA contacted the Principal Maintenance Inspector (PMI) to determine whether the replacement had been accomplished on that operator's affected airplanes. The PMI verified that the service bulletin had been accomplished on all affected airplanes in that operator's fleet.

In addition, the airplane manufacturer has also updated the Illustrated Parts Catalog to include the washer that corrects the unsafe condition in the seat assembly; therefore, the unsafe condition is not likely to be reintroduced in the future.

FAA's Conclusions

Based upon the FAA's review of the data submitted by the affected operators and the airplane manufacturer, the FAA has determined that the previously identified unsafe condition no longer exists. Accordingly, the proposed rule is hereby withdrawn.

Withdrawal of this notice of proposed rulemaking constitutes only such action, and does not preclude the agency from issuing another notice in the future, nor does it commit the agency to any course of action in the future.

Regulatory Impact

Since this action only withdraws a notice of proposed rulemaking, it is neither a proposed nor a final rule and therefore, is not covered under Executive Order 12866, the Regulatory Flexibility Act, or DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979).

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Withdrawal

Accordingly, the notice of proposed rulemaking, Docket 96–NM–206–AD, published in the **Federal Register** on June 6, 1997 (62 FR 31020), is withdrawn.

Issued in Renton, Washington, on August 13, 1999.

D. L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–21574 Filed 8–18–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–351–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 737–300, –400, and –500 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all Boeing Model 737–300, –400 and –500 series airplanes. This proposal would require replacement, with new parts, of the existing actuators or the rod ends on the existing actuators at wing leading edge slat positions 1, 2, 5, and 6. This proposal is prompted by reports indicating that the rod ends on several leading edge slat actuators have fractured. The actions specified by the proposed AD are intended to prevent fatigue cracking of the rod ends of the leading edge slat actuators, which could result in uncommanded deployment of the wing leading edge slat and consequent reduced controllability of the airplane.

DATES: Comments must be received by October 4, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–351–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00

p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Robert C. Jones, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone (425) 227–1118; fax (425) 227–1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 98–NM–351–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–351–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received reports of fractured rod ends on several actuators for the wing leading edge slats on Boeing Model 737–300, –400, and –500 series airplanes. One reported case of an actuator rod end fracture resulted in an air turnback after the airplane experienced uncommanded roll during flight. It has been determined that these fractures are the result of fatigue cracking. Failure of the actuator rod end, under certain flight conditions, could result in an uncommanded deployment of the affected wing leading edge slat and consequent reduced controllability of the airplane.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletin 737–27A1211, dated November 19, 1998, which describes procedures for replacement of the existing wing leading edge slat actuator with a new actuator, or replacement of the rod end on the existing leading edge slat actuator. Accomplishment of either of these actions specified in the alert service bulletin is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the alert service bulletin described previously.

Cost Impact

There are approximately 1,897 airplanes of the affected design in the worldwide fleet. The FAA estimates that 720 airplanes of U.S. registry would be affected by this proposed AD.

Replacement of the leading edge slat actuator with an actuator that has a new rod end is proposed as one option for compliance with this AD action. Replacement of the actuators on slat positions 1, 2, 5, and 6 would take approximately 3 hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts cost approximately $32,252 per airplane. Based on these figures, the cost impact of the installation of actuators with new rod ends as proposed as an option by this AD on U.S. operators is estimated to be $32,432 per airplane.

In lieu of installation of an actuator with a new rod end, this proposed AD provides an option for replacement of the rod ends on the existing actuators. This action would take approximately 4 work hours per airplane, at an average labor rate of $60 per work hour. Required parts would cost between approximately $5,928 and $21,544 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be between $6,168 and $21,784 per airplane.

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

Regulatory Impact

The regulations proposed herein would 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 proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Boeing: Docket 98–NM–351–AD.

Applicability: Model 737–300, –400, and –500 series airplanes; line numbers 1001 through 3063 inclusive; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously. To prevent fatigue cracking of the rod ends on the leading edge slat actuators, which could result in uncommanded deployment of the wing leading edge slat and consequent reduced controllability of the airplane, accomplish the following:

(a) Within 24 months after the effective date of this AD: Replace the leading edge slat actuator with an actuator that has a new rod end, or replace the rod end on the existing slat actuator with a new rod end, at slat positions 1, 2, 5, and 6; in accordance with the Accomplishment Instructions in Boeing Alert Service Bulletin 737–27A1211, dated November 19, 1998.

Spares

(b) As of the effective date of this AD, no person shall install any part having a part number identified in the ''Existing Part Number'' column of Section 2.E. of Boeing Alert Service Bulletin 737–27A1211, dated November 19, 1998, on any airplane.

Alternative Methods of Compliance

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

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

Special Flight Permits

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

Issued in Renton, Washington, on August 13, 1999.

D. L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–21575 Filed 8–18–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 206

RIN 1010–AC59

Valuation of Federal Geothermal Resources

AGENCY: Minerals Management Service, Interior.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: In response to deregulation of the electric power market in California and resulting changes to the geothermal industry, the Minerals Management Service (MMS) is considering amending its regulations regarding the valuation, for royalty purposes, of Federal geothermal resources used to generate electricity. MMS specifically seeks comments on the use of the netback procedure to value geothermal resources that are not sold under arm's-length contracts, whether the existing netback procedure should be modified, and whether there are reasonable alternatives to netback valuation. MMS also seeks comments on any other aspects of the rules including the rules governing valuation of resources used in direct utilization processes, particularly alternatives for valuing those resources that are not subject to a sales transaction.

DATES: Comments must be received on or before October 18, 1999.

ADDRESSES: The mailing address for written comments regarding geothermal valuation issues is David S. Guzy, Chief, Rules and Publications Staff, Minerals Management Service, Royalty Management Program, P.O. Box 25165, MS 3021, Denver, Colorado 80225. Courier address is Building 85, Room A–613, Denver Federal Center, Denver, Colorado 80225. E-mail address is RMP.comments@mms.gov. For additional details, see **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: David S. Guzy, Chief, Rules and Publications Staff, MMS, Royalty Management Program, at telephone (303) 231–3432, FAX (303) 231–3385, or e-mail david.guzy@mms.gov.

SUPPLEMENTARY INFORMATION:

Public Comment Procedure: If you wish to comment, you may submit your comments by any one of several methods. You may mail comments to David S. Guzy, Chief, Rules and Publications Staff, Minerals Management Service, Royalty Management Program, P.O. Box 25165, MS 3021, Denver, CO 80225–0165. Courier or overnight delivery address is Building 85, Room A–613, Denver Federal Center, Denver, Colorado 80225. You may also comment via the Internet to RMP.comments@mms.gov. Please submit Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include ''Attn.: RIN 1010–AC59'' and your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, contact David S. Guzy directly at (303) 231–3432.

We will post public comments after the comment period closes on the Internet at *http://www.rmp.mms.gov.* You may arrange to view paper copies of the comments by contacting David S. Guzy, Chief, Rules and Publications Staff, telephone (303)231–3432, FAX (303)231–3385. Our practice is to make comments, including names and addresses of respondents, available for public review on the Internet and during regular business hours at our offices in Lakewood, Colorado. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

I. Background

The Geothermal Steam Act of 1970, as amended (30 U.S.C. 1001–1025), requires the lessee to pay royalty to the United States on the amount or value of steam, or any other form of heat or energy derived from production under the lease and sold or used by the lessee or reasonably susceptible to sale or use by the lessee. Federal geothermal leases

reserve to the Secretary considerable discretion to determine value for royalty purposes. As steward of the Nation's public resources, the Secretary is responsible for ensuring that the public receives a fair return—in the form of royalties—in exchange for the lessee's exclusive right and privilege to extract and use geothermal resources produced from Federal leases. The value of geothermal resources for royalty purposes is defined by regulation in 30 CFR part 206. The purpose of this Advance Notice of Proposed Rulemaking is to solicit comments on possible new methods of determining the royalty value of Federal geothermal resources. We also seek comments on other aspects of the geothermal rules. We will consider the comments received in response to this Advance Notice in developing a proposed rulemaking, which MMS would publish in the **Federal Register**.

We are specifically requesting comments on the netback valuation procedure defined in 30 CFR 206.353 and 206.354 (1998) and whether there are reasonable alternatives to that procedure. The netback procedure derives the value of the geothermal resource by subtracting the lessee's costs of generating and transmitting electricity from the lessee's revenue received for the sale of electricity. The amount remaining from this calculation is the value of the geothermal resource upon which royalty is due. (You can find a detailed description of the netback procedure in MMS's ''Geothermal Payor Handbook-Product Valuation'' at www.rmp.mms.gov/custserv/pubserv/handbook.htm.) Netback is now the most widely used method to value Federal geothermal resources.

Application of the netback method in the deregulated California electric power market has resulted in a dramatic decrease in geothermal royalty payments. When the current geothermal rules were adopted in 1992, electricity generated by geothermal resources was subject to incentive pricing. Because of this incentive and the inherent risk involved in developing geothermal resources, the Department allowed a generous rate of return in the netback calculation. However, this incentive pricing is no longer being paid, and we are concerned about whether twice the Standard and Poor's BBB industrial bond rate is still the appropriate rate of return to use in the netback calculation.

Over the past 2 years, State and county agencies that share in this royalty are seeing losses in royalty revenue from 50 percent to over 95 percent. County officials have told MMS that they do not have a ready source of replacement funds. Members of Congress have also become alarmed at the declining royalties and have asked us to expeditiously reevaluate our geothermal valuation regulations to assure taxpayers a fair return for their resources.

II. Goals of Valuation Alternatives

The goals of any proposed alternative to the current netback procedure, whether a modification to the existing netback procedure or a completely different valuation method, should be twofold. First, the proposed method should derive a value of the resource that reflects its market value. Second, the proposed method should be easy to apply and readily verifiable.

To achieve these goals, we pose the following questions:

1. Should we modify the netback procedure and, if so, how?

2. Should we abandon the netback procedure in favor of an alternative valuation method?

3. What are the alternative methods to value geothermal resources that are not subject to a sales transaction? (Note that reliance on comparable arm's-length sales is not a viable alternative because in most cases there are no arm's-length sales of Federal geothermal resources that could be used to establish value.)

If you propose an alternative valuation method, please describe it in sufficient detail to provide an understanding of its workings and effects. Please use examples where possible.

III. Possible Alternative Valuation Methods

As a starting point for discussion, we request comments on the following possible alternatives:

(a) Modification of the existing netback valuation procedure.

Two areas where the existing netback procedure might be modified are: (1) reducing the rate of return on capital investments; and (2) reducing the limits on deductions. The current rate of return, twice the Standard and Poor's industrial BBB bond rate, yields an annual return on power plant and transmission investments of about 15 percent at current rates. We ask what rationale exists to reduce this rate and, if so, to what standard (for example, 1 × BBB, 1.5 × BBB, another index, etc.).

MMS currently limits the combined generating and transmission deductions to 99 percent of the lessee's monthly gross proceeds for the sale of electricity. Should this limit be reduced and, if so, to what amount?

We are also interested in suggestions for other modifications to the netback procedure.

(b) A ''rate-of-return'' method.

This method would use discounted cash flow analyses (DCFs) to determine a resource value that yields the same rate of return for both the resource recovery and power plant portions of the geothermal project. This would ensure that, for royalty purposes, an equal portion of the total return from a combined geothermal resource recovery and electricity generating operation would be allocated to the resource recovery activity.

The lessee would prepare separate DCFs for both the resource recovery and power plant portions of the project using its actual costs associated with developing and operating each portion. DCFs for the resource recovery would assume a range of geothermal resource values to represent expected income for the field. DCFs for the power plant would assume a range of geothermal resource values to represent the cost of purchasing the resource, and a range of electricity prices to represent expected income.

Starting with a given electricity price for the power plant, the lessee would repeat the DCFs for each project portion over the range of resource values until the rate of return for the resource recovery operation equals the rate of return for the power plant. The lessee would repeat the DCFs over the range of expected electricity prices to determine the relationship between electricity price and resource value. The value of the geothermal resource equals the cost of purchasing the geothermal resource when the rates of return for both portions are the same.

We request comments and analyses of the feasibility of using the ''rate-of-return'' method for valuing geothermal resources. We also ask for suggested improvements to this method.

(c) A ''percentage-of-revenue'' method.

This method would set the value of the geothermal resource as a percentage of the electricity value. In most cases the electricity value would be the lessee's total revenue received for the sale of electricity and other generating services. We ask what percentages are reasonable and how they are determined. We also ask whether the percentages should be fixed or whether they should vary with time or price of electricity, such as a step or sliding scale.

Again, we offer these alternatives as a starting point for discussion. We invite you to suggest other valuation methods not presented here.

IV. Valuation of Resources Used in Direct Utilization Processes

We also solicit comments on the valuation standards for direct utilization at 30 CFR 206.355, particularly options for the ''alternative fuel'' method used to value geothermal resources that are not subject to a sales transaction. Proposed alternative methods should satisfy the valuation goals discussed above.

V. Other Comments

MMS also seeks comments on any other aspects of the rules.

Dated: August 13, 1999.

Shayla Freeman Simmons,

Acting Assistant Secretary, Land and Minerals Management.

[FR Doc. 99–21506 Filed 8–18–99; 8:45 am]

BILLING CODE 4310–MR–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 009–0143b; FRL–6420–5]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revisions for Six California County Air Pollution Control Districts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the California State Implementation Plan (SIP) which concern the control of particulate matter (PM) emissions from open burning, incinerator burning, and orchard heater sources. The intended effect of this action is to regulate emissions of PM in accordance with 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 approving the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision and anticipates no adverse comments. A detailed rationale for this proposed approval is set forth in the direct final rule. If no relevant adverse comments are received, no further activity is contemplated in relation to this rule. If EPA receives relevant adverse comments, the direct final rule will not take effect and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this rule. Any parties interested in commenting on this rule should do so at this time.

DATES: Comments must be received in writing by September 20, 1999.

ADDRESSES: Written comments should be addressed to: Andrew Steckel, Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Copies of the rules and EPA's evaluation report for the rules are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rules are also available for inspection at the following locations:

California Air Resources Board, Stationary Source Divison, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812

Kern County Air Pollution Control District, 2700 ''M'' Street, Suite 290, Bakersfield, CA 93301

Northern Sierra Air Quality Management District, 540 Searles Avenue, Nevada City, CA 95959

Siskiyou County Air Pollution Control District, 525 South Foothill Drive, Yreka, CA 96097

San Joaquin Valley Unified Air Pollution Control District, 1990 East Gettysburg Street, Fresno, CA 93726

Tehama County Air Pollution Control District, 1760 Walnut Street, Red Bluff, CA 96080

Tuolumne County Air Pollution Control District, 2 South Green Street, Sonora, CA 95370

FOR FURTHER INFORMATION CONTACT: Al Petersen, Rulemaking Office, (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1135.

SUPPLEMENTARY INFORMATION:

I. Applicability

This document concerns the following rules submitted by the California Air Resources Board:

- Kern County Air Pollution Control District Rule 416, Open Burning (submitted on October 18, 1996).
- Kern County Air Pollution Control District Rule 417, Agricultural Burning (submitted on October 18, 1996).
- Northern Sierra Air Quality Management District Rules 302 to 312, Open Burning (submitted on October 25, 1991).
- San Joaquin Valley Unified Air Pollution Control District Rule 4302, Incinerator Burning (submitted on May 24, 1994).
- San Joaquin Valley Unified Air Pollution Control District Rule 4303, Orchard Heaters (submitted on May 24, 1994).
- Siskiyou County Air Pollution Control District Rule 4.3, Non-Agricultural Burning (submitted on March 26, 1990).
- Tehema County Air Pollution Control District Rule 3.12, Wildland Vegetation Management Burning, (submitted on May 13, 1991).
- Tuolumne County Air Pollution Control District Rules 302 to 310, Open Burning (submitted on March 26, 1990).

For further information, please see the information provided in the Direct Final action that is located in the Rules section of this **Federal Register**.

Dated: July 30, 1999.

David P. Howekamp,

Acting Regional Administrator, Region IX.

[FR Doc. 99–21165 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 126–163b; FRL–6420–1]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision; South Coast Air Quality Management District; Ventura County Air Pollution Control District; Mojave Desert Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve revisions to the California State Implementation Plan (SIP). Two rules to be approved into the SIP control volatile organic compound (VOC) emissions from storage tank cleaning and degassing operations and from components at crude oil and natural gas production and processing facilities. Two rules to be removed from the SIP control VOC emissions from pumps, compressors, and relief valves.

The intended effect of this action is to regulate emissions of VOCs in accordance with 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 approving the state's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision and anticipates no adverse comments. A detailed rationale for this approval is set forth in the direct final rule. If no adverse comments are received, no further activity is contemplated. 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. Any parties interested in commenting should do so at this time.

DATES: Written comments must be received by September 20, 1999.

ADDRESSES: Comments should be addressed to: Andrew Steckel, Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Copies of the rules and EPA's evaluation report of each rule are available for public inspection at EPA's Region 9 office during normal business hours. Copies of the submitted rules are also available for inspection at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812

South Coast Air Quality Management District, 21865 E. Copley Drive, Diamond Bar, CA 91765–4182

Ventura County Air Pollution Control District, 702 County Square Drive, Ventura, CA 93003

Mojave Desert Air Quality Management District, 15428 Civic Drive, Suite 200, Victorville, CA 92392–2383

FOR FURTHER INFORMATION CONTACT: Max Fantillo, Rulemaking Office, AIR–4, Air Division, U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105–3901, Telephone: (415) 744–1183.

SUPPLEMENTARY INFORMATION: This document concerns South Coast Air Quality Management District's (SCAQMD) Rule 1149, Storage Tank Cleaning and Degassing and Ventura County Air Pollution Control District's (VCAPCD) Rule 74.10, Components at Crude Oil and Natural Gas Production and Processing Facilities. The rules being removed from the SIP are Mojave Desert Air Quality Management District's (MDAQMD) Rules 466, Pumps and Compressors and 467, Safety Pressure Relief Valves. These rules were submitted by the California Air Resources Board (CARB) to EPA on October 13, 1995 (Rule 1149), June 23, 1998 (Rule 74.10), and November 30, 1994 (Rules 466 and 467). For further information, please see the information provided in the direct final action that is located in the rules section of this **Federal Register**.

Dated: July 30, 1999.

David P. Howekamp,

Acting Regional Administrator, Region IX.

[FR Doc. 99–21163 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 172–0157b; FRL–6420–2]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision: Bay Area Air Quality Management District, Kern County Air Pollution Control District, Monterey Bay Unified Air Pollution Control District, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is approving revisions to the California State Implementation Plan (SIP) which concern the control of volatile organic compound (VOC) emissions from the miscellaneous metal part and magnet wire coating industries. The intended effect of this action is to regulate emissions of VOCs according to 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 approving the state's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision and anticipates no adverse comments. A detailed rationale for this approval is set forth in the direct final rule. If no adverse comments are received, no further activity is contemplated. 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. Any parties interested in commenting should do so at this time.

DATES: Written comments must be received by September 20, 1999.

ADDRESSES: Comments should be addressed to: Andrew Steckel, Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Copies of the rule revisions and EPA's evaluation report of each rule are available for public inspection at EPA's Region 9 office during normal business hours. Copies of the submitted rule revisions are also available for inspection at the following locations:

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

Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, SW, Washington, D.C. 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812

Bay Area Air Quality Management District, 939 Ellis Street, San Francisco, CA 94109

Kern County Air Pollution Control District, 2700 M Street, Suite 302, Bakersfield, CA 93301

Monterey Bay Unified Air Pollution Control District, 24580 Silver Cloud Court, Monterey, CA 93940

South Coast Air Quality Management District, 218 East Copley Drive, Diamond Bar, CA 91765

FOR FURTHER INFORMATION CONTACT: Jerald S. Wamsley, Rulemaking Office, AIR–4, Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1226.

SUPPLEMENTARY INFORMATION: This document concerns the following rules:

—Bay Area Air Quality Management District (BAAQMD)—Rule 8–26, Magnet Wire Coating Operations;

—Kern County Air Pollution Control District (KCAPCD)—Rule 410.4, Surface Coating of Metal Parts and Products;

—Monterey Bay Unified Air Pollution Control District (MBUAPCD)—Rule 434, Coating of Metal Parts and Products; and,

—South Coast Air Quality Management District (SCAQMD)—Rule 1107, Coating of Metal Parts and Products.

These rules were submitted by the California Air Resources Board (CARB) to EPA on July 23, 1996 (BAAQMD Rule 8–26), May 10, 1996 (KCAPCD 410.4), March 3, 1997 (MBUAPCD Rule 434), February 16, 1999 (SCAQMD Rule 1107).

For further information, please see the information provided in the direct final action that is located in the rules section of this **Federal Register**.

Dated: July 30, 1999.

David P. Howekamp,

Acting Regional Administrator, Region IX.

[FR Doc. 99–21161 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD077–3034b; FRL–6418–9]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Control of VOC Emissions From Reinforced Plastics Manufacturing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of Maryland for the purpose of establishing reasonably available control technology (RACT) for Volatile Organic Compound (VOC) emissions from reinforced plastic manufacturing. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A description of the state submittal and EPA's evaluation are in the Technical Support Document (TSD) prepared in support of this rulemaking. A copy is available, upon request, from the Regional Office listed in the **ADDRESSES** section of this document. If no adverse comments are received in response to this action, no further activity is contemplated. 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. 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.

DATES: Comments must be received in writing by September 20, 1999.

ADDRESSES: Written comments should be addressed to Walter Wilkie, Chief, Technical Assessment Branch, Mailcode 3AP22, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland, 21224.

FOR FURTHER INFORMATION CONTACT: Walter Wilkie (215) 814–2150 at the EPA Region III address above, or by e-mail at wilkie.walter@.epa.gov.

SUPPLEMENTARY INFORMATION: For additional information, please see the information in the direct final action, with the same title, that is located in the ''Rules and Regulations'' section of this **Federal Register** publication.

Dated: August 2, 1999.

W. Michael McCabe,

Regional Administrator, Region III.

[FR Doc. 99–21159 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 55

[FRL–6422–9]

Outer Continental Shelf Air Regulations; Consistency Update for California

AGENCY: Environmental Protection Agency (''EPA'').

ACTION: Proposed rule—consistency update.

SUMMARY: EPA is proposing to update a portion of the Outer Continental Shelf (''OCS'') Air Regulations. Requirements applying to OCS sources located within 25 miles of states' seaward boundaries must be updated periodically to remain consistent with the requirements of the corresponding onshore area (''COA''), as mandated by section 328(a)(1) of the Clean Air Act, as amended in 1990 (''the Act''). The portion of the OCS air regulations that is being updated pertains to the requirements for OCS sources for which the San Luis Obispo County Air Pollution Control District (San Luis Obispo County APCD) and Ventura County Air Pollution Control District (Ventura County APCD) are the designated COAs. The intended effect of approving the OCS requirements for the above Districts, contained in the Technical Support Document, is to regulate emissions from OCS sources in accordance with the requirements onshore. The changes to the existing requirements discussed below are proposed to be incorporated by reference into the Code of Federal Regulations and are listed in the appendix to the OCS air regulations.

DATES: Comments must be received on or before September 20, 1999.

ADDRESSES: Comments must be mailed (in duplicate if possible) to: EPA Air Docket (Air–4), Attn.: Docket No. A–93–16 Section XVIII, Environmental Protection Agency, Air Division, Region 9, 75 Hawthorne St., San Francisco, CA 94105.

DOCKET: Supporting information used in developing the rule and copies of the documents EPA is proposing to incorporate by reference are contained in Docket No. A–93–16 Section XVIII. This docket is available for public inspection and copying Monday–Friday during regular business hours at the following locations:

EPA Air Docket (Air–4), Attn.: Docket No. A–93–16 Section XVIII, Environmental Protection Agency, Air Division, Region 9, 75 Hawthorne St., San Francisco, CA 94105.

EPA Air Docket (LE–131), Attn.: Air Docket No. A–93–16 Section XVIII, Environmental Protection Agency, 401 M Street SW, Room M–1500, Washington, DC 20460.

A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Christine Vineyard, Air Division (Air–4), U.S. EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105, (415) 744–1197.

SUPPLEMENTARY INFORMATION:

I. Background

On September 4, 1992, EPA promulgated 40 CFR part 55 [1], which established requirements to control air pollution from OCS sources in order to attain and maintain federal and state ambient air quality standards and to comply with the provisions of part C of title I of the Act. Part 55 applies to all OCS sources offshore of the States except those located in the Gulf of Mexico west of 87.5 degrees longitude. Section 328 of the Act requires that for such sources located within 25 miles of a state's seaward boundary, the requirements shall be the same as would be applicable if the sources were located in the COA. Because the OCS requirements are based on onshore requirements, and onshore requirements may change, section 328(a)(1) requires that EPA update the OCS requirements as necessary to maintain consistency with onshore requirements.

Pursuant to § 55.12 of the OCS rule, consistency reviews will occur (1) at least annually; (2) upon receipt of a Notice of Intent under § 55.4; or (3) when a state or local agency submits a rule to EPA to be considered for incorporation by reference in part 55. This proposed action is being taken in

[1] The reader may refer to the Notice of Proposed Rulemaking, December 5, 1991 (56 FR 63774), and the preamble to the final rule promulgated September 4, 1992 (57 FR 40792) for further background and information on the OCS regulations.

response to the submittal of rules by two local air pollution control agencies. Public comments received in writing within 30 days of publication of this document will be considered by EPA before publishing a final rule.

Section 328(a) of the Act requires that EPA establish requirements to control air pollution from OCS sources located within 25 miles of states' seaward boundaries that are the same as onshore requirements. To comply with this statutory mandate, EPA must incorporate applicable onshore rules into part 55 as they exist onshore. This limits EPA's flexibility in deciding which requirements will be incorporated into part 55 and prevents EPA from making substantive changes to the requirements it incorporates. As a result, EPA may be incorporating rules into part 55 that do not conform to all of EPA's state implementation plan (SIP) guidance or certain requirements of the Act. Consistency updates may result in the inclusion of state or local rules or regulations into part 55, even though the same rules may ultimately be disapproved for inclusion as part of the SIP. Inclusion in the OCS rule does not imply that a rule meets the requirements of the Act for SIP approval, nor does it imply that the rule will be approved by EPA for inclusion in the SIP.

II. EPA Evaluation and Proposed Action

In updating 40 CFR part 55, EPA reviewed the rules submitted for inclusion in part 55 to ensure that they are rationally related to the attainment or maintenance of federal or state ambient air quality standards or part C of title I of the Act, that they are not designed expressly to prevent exploration and development of the OCS and that they are applicable to OCS sources. 40 CFR 55.1. EPA has also evaluated the rules to ensure they are not arbitrary or capricious. 40 CFR 55.12 (e). In addition, EPA has excluded administrative or procedural rules,[2] and requirements that regulate toxics which are not related to the attainment and maintenance of federal and state ambient air quality standards.

A. After review of the rule submitted by San Luis Obispo County APCD against the criteria set forth above and in 40 CFR part 55, EPA is proposing to make the following rules applicable to OCS sources for which the San Luis Obispo County APCD is designated as the COA:

Rule 105 Definitions (Revised 1/24/96)
Rule 201 Equipment Not Requiring a Permit (Revised 4/26/95)
Rule 302 Schedule of Fees (Revised 6/18/97)
Rule 405 Nitrogen Oxides Emission Standard, Limitations, and Prohibitions (Revised 11/16/93)
Rule 407 Organic Material Emission Standards (Revised 5/22/96)
Rule 411 Surface Coating of Metal Parts and Products (Revised 1/28/98)
Rule 419 Petroleum Pits, Ponds, Sumps, Well Cellars, and Wastewater Separators (Revised 7/12/94)
Rule 425 Storage of Volatile Organic Compounds (Adopted 7/12/94)
Rule 427 Marine Tanker Loading (Adopted 4/26/95)
Rule 429 Oxides of Nitrogen and Carbon Monoxide Emissions from Electric Power Generation Boilers, (Revised 11/12/97)
Rule 430 Control of Oxides of Nitrogen from Industrial, Institutional, Commercial Boilers, Steam Generators, and Process Heaters (Adopted 7/26/95)
Rule 431 Stationary Internal Combustion Engines (Adopted 11/13/96)
Rule 601 New Source Performance Standards (Revised 5/28/97)

1. *The following San Luis Obispo County APCD rule will be removed from part 55:*

Rule 104 Action in Areas of High Concentration (Repealed 3/26/97)

B. After review of the rules submitted by Ventura County APCD against the criteria set forth above and in 40 CFR part 55, EPA is proposing to make the following rules applicable to OCS sources for which the Ventura County APCD is designated as the COA.

1. *The following rules were submitted as revisions to existing requirements:*

Rule 42 Permit Fees (Revised 6/22/99)
Rule 64 Sulfur Content of Fuels (Revised 4/13/99)

2. *The following new rules were submitted:*

Rule 57 Source Test, Emission Monitor, and Call-Back Fees (Adopted 6/22/99)

3. *The following rule was submitted but will not be incorporated into part 55:*

Rule 221 Transportation Conformity (Adopted 6/8/99)

III. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, Regulatory Planning and Review.

B. Executive Order 12875

Under Executive Order 12875, Enhancing the Intergovernmental Partnership, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, EPA may

[2] Each COA which has been delegated the authority to implement and enforce part 55, will use its administrative and procedural rules as onshore. However, in those instances where EPA has not delegated authority to implement and enforce part 55, EPA will use its own administrative and procedural requirements to implement the substantive requirements. 40 CFR 55.14(c)(4).

not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because 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 create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of 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).

F. 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 annual 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 annual 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.

List of Subjects in 40 CFR Part 55

Environmental protection, Administrative practice and procedures, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Nitrogen oxides, Outer Continental Shelf, Ozone, Particulate matter, Permits, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: August 6, 1999.

Laura Yoshii,

Acting Regional Administrator, Region IX.

Title 40 of the Code of Federal Regulations, part 55, is proposed to be amended as follows:

PART 55—[AMENDED]

1. The authority citation for part 55 continues to read as follows:

Authority: Section 328 of the Clean Air Act (42 U.S.C. 7401 *et seq.*) as amended by Public Law 101–549.

2. Section 55.14 is proposed to be amended by revising paragraphs (e)(3)(ii)(E) and (e)(3)(ii)(H) to read as follows:

§ 55.14 Requirements that apply to OCS sources located within 25 miles of States seaward boundaries, by State.

* * * * *

(e) * * *

(3) * * *

(ii) * * *

(E) *San Luis Obispo County Air Pollution Control District Requirements Applicable to OCS Sources.*

* * * * *

(H) *Ventura County Air Pollution Control District Requirements Applicable to OCS Sources.*

* * * * *

3. Appendix A to CFR Part 55 is proposed to be amended by revising paragraph (b)(5) and (8) under the heading ''California'' to read as follows:

Appendix A to Part 55—Listing of State and Local Requirements Incorporated by Reference Into Part 55, by State

* * * * *

California

* * * * *

(b) Local requirements.

* * * * *

(5) The following requirements are contained in *San Luis Obispo County Air Pollution Control District Requirements Applicable to OCS Sources,* July 12, 1999:

Rule 103 Conflicts Between District, State and Federal Rules (Adopted 8/6/76)
Rule 104 Action in Areas of High Concentration (Repealed 3/26/97)
Rule 105 Definitions (Adopted 1/24/96)
Rule 106 Standard Conditions (Adopted 8/6/76)
Rule 108 Severability (Adopted 11/13/84)
Rule 113 Continuous Emissions Monitoring, except F. (Adopted 7/5/77)
Rule 201 Equipment not Requiring a Permit, except A.1.b. (Revised 4/26/95)
Rule 202 Permits, except A.4. and A.8. (Adopted 11/5/91)
Rule 203 Applications, except B. (Adopted 11/5/91)
Rule 204 Requirements, except B.3. and C. (Adopted 8/10/93)
Rule 209 Provision for Sampling and Testing Facilities (Adopted 11/5/91)
Rule 210 Periodic Inspection, Testing and Renewal of Permits to Operate (Adopted 11/5/91)
Rule 213 Calculations, except E.4. and F. (Adopted 8/10/93)
Rule 302 Schedule of Fees (Adopted 6/18/97)
Rule 305 Fees for Major Non-Vehicular Sources (title change—Adopted 9/15/92)
Rule 401 Visible Emissions (Adopted 8/6/76)
Rule 403 Particulate Matter Emissions (Adopted 8/6/76)
Rule 404 Sulfur Compounds Emission Standards, Limitations and Prohibitions (Revised 12/6/76)

Rule 405 Nitrogen Oxides Emission Standards, Limitations and Prohibitions (Adopted 11/16/93)
Rule 406 Carbon Monoxide Emission Standards, Limitations and Prohibitions (Adopted 11/14/84)
Rule 407 Organic Material Emission Standards, Limitations and Prohibitions (Adopted 5/22/96)
Rule 411 Surface Coating of Metal Parts and Products (Adopted 1/28/98)
Rule 416 Degreasing Operations (Adopted 6/18/79)
Rule 417 Control of Fugitive Emissions of Volatile Organic Compounds (Adopted 2/9/93)
Rule 419 Petroleum Pits, Ponds, Sumps, Well Cellars, and Wastewater Separators (Revised 7/12/94)
Rule 422 Refinery Process Turnarounds (Adopted 6/18/79)
Rule 425 Storage of Volatile Organic Compounds (Adopted 7/12/94)
Rule 427 Marine Tanker Loading (Adopted 4/26/95)
Rule 429 Oxides of Nitrogen and Carbon Monoxide Emissions from Electric Power Generation Boilers, (Revised 11/12/97)
Rule 430 Control of Oxides of Nitrogen from Industrial, Institutional, Commercial Boilers, Steam Generators, and Process Heaters (Adopted 7/26/95)
Rule 431 Stationary Internal Combustion Engines (Adopted 11/13/96)
Rule 501 General Burning Provisions (Adopted 1/10/89)
Rule 503 Incinerator Burning, except B.1.a. (Adopted 2/7/89)
Rule 601 New Source Performance Standards (Adopted 5/28/97)

* * * * *

(8) The following requirements are contained in Ventura County Air Pollution Control District Requirements Applicable to OCS Sources:

Rule 2 Definitions (Adopted 11/10/98)
Rule 5 Effective Date (Adopted 5/23/72)
Rule 6 Severability (Adopted 11/21/78)
Rule 7 Zone Boundaries (Adopted 6/14/77)
Rule 10 Permits Required (Adopted 6/13/95)
Rule 11 Definition for Regulation II (Adopted 6/13/95)
Rule 12 Application for Permits (Adopted 6/13/95)
Rule 13 Action on Applications for an Authority to Construct (Adopted 6/13/95)
Rule 14 Action on Applications for a Permit to Operate (Adopted 6/13/95)
Rule 15.1 Sampling and Testing Facilities (Adopted 10/12/93)
Rule 16 BACT Certification (Adopted 6/13/95)
Rule 19 Posting of Permits (Adopted 5/23/72)
Rule 20 Transfer of Permit (Adopted 5/23/72)
Rule 23 Exemptions from Permits (Adopted 7/9/96)
Rule 24 Source Recordkeeping, Reporting, and Emission Statements (Adopted 9/15/92)
Rule 26 New Source Review (Adopted 10/22/91)
Rule 26.1 New Source Review—Definitions (Adopted 10/22/91)
Rule 26.2 New Source Review—Requirements (Adopted 10/22/91)
Rule 26.3 New Source Review—Exemptions (Adopted 10/22/91)
Rule 26.6 New Source Review—Calculations (Adopted 10/22/91)
Rule 26.8 New Source Review—Permit To Operate (Adopted 10/22/91)
Rule 26.10 New Source Review—PSD (Adopted 10/22/91)
Rule 28 Revocation of Permits (Adopted 7/18/72)
Rule 29 Conditions on Permits (Adopted 10/22/91)
Rule 30 Permit Renewal (Adopted 5/30/89)
Rule 32 Breakdown Conditions: Emergency Variances, A., B.1., and D. only. (Adopted 2/20/79)
Rule 33 Part 70 Permits—General (Adopted 10/12/93)
Rule 33.1 Part 70 Permits—Definitions (Adopted 10/12/93)
Rule 33.2 Part 70 Permits—Application Contents (Adopted 10/12/93)
Rule 33.3 Part 70 Permits—Permit Content (Adopted 10/12/93)
Rule 33.4 Part 70 Permits—Operational Flexibility (Adopted 10/12/93)
Rule 33.5 Part 70 Permits—Time frames for Applications, Review and Issuance (Adopted 10/12/93)
Rule 33.6 Part 70 Permits—Permit Term and Permit Reissuance (Adopted 10/12/93)
Rule 33.7 Part 70 Permits—Notification (Adopted 10/12/93)
Rule 33.8 Part 70 Permits—Reopening of Permits (Adopted 10/12/93)
Rule 33.9 Part 70 Permits—Compliance Provisions (Adopted 10/12/93)
Rule 33.10 Part 70 Permits—General Part 70 Permits (Adopted 10/12/93)
Rule 34 Acid Deposition Control (Adopted 3/14/95)
Rule 35 Elective Emission Limits (Adopted 11/12/96)
Rule 36 New Source Review—Hazardous Air Pollutants (Adopted 10/6/98)
Appendix II–B.—Best Available Control Technology (BACT) Tables (Adopted 12/86)
Rule 42 Permit Fees (Adopted 6/22/99)
Rule 44 Exemption Evaluation Fee (Adopted 9/10/96)
Rule 45 Plan Fees (Adopted 6/19/90)
Rule 47 Source Test, Emission Monitor, and Call-Back Fees (Adopted 6/22/99)
Rule 45.2 Asbestos Removal Fees (Adopted 8/4/92)
Rule 50 Opacity (Adopted 2/20/79)
Rule 52 Particulate Matter—Concentration (Adopted 5/23/72)
Rule 53 Particulate Matter—Process Weight (Adopted 7/18/72)
Rule 54 Sulfur Compounds (Adopted 6/14/94)
Rule 56 Open Fires (Adopted 3/29/94)
Rule 57 Combustion Contaminants—Specific (Adopted 6/14/77)
Rule 60 New Non-Mobile Equipment—Sulfur Dioxide, Nitrogen Oxides, and Particulate Matter (Adopted 7/8/72)
Rule 62.7 Asbestos—Demolition and Renovation (Adopted 6/16/92)
Rule 63 Separation and Combination of Emissions (Adopted 11/21/78)
Rule 64 Sulfur Content of Fuels (Adopted 4/13/99)
Rule 67 Vacuum Producing Devices (Adopted 7/5/83)
Rule 68 Carbon Monoxide (Adopted 6/14/77)
Rule 71 Crude Oil and Reactive Organic Compound Liquids (Adopted 12/13/94)
Rule 71.1 Crude Oil Production and Separation (Adopted 6/16/92)
Rule 71.2 Storage of Reactive Organic Compound Liquids (Adopted 9/26/89)
Rule 71.3 Transfer of Reactive Organic Compound Liquids (Adopted 6/16/92)
Rule 71.4 Petroleum Sumps, Pits, Ponds, and Well Cellars (Adopted 6/8/93)
Rule 71.5 Glycol Dehydrators (Adopted 12/13/94)
Rule 72 New Source Performance Standards (NSPS) (Adopted 9/10/96)
Rule 74 Specific Source Standards (Adopted 7/6/76)
Rule 74.1 Abrasive Blasting (Adopted 11/12/91)
Rule 74.2 Architectural Coatings (Adopted 08/11/92)
Rule 74.6 Surface Cleaning and Degreasing (Adopted 11/10/98)
Rule 74.6.1 Cold Cleaning Operations (Adopted 7/9/96)
Rule 74.6.2 Batch Loaded Vapor Degreasing Operations (Adopted 7/9/96)
Rule 74.7 Fugitive Emissions of Reactive Organic Compounds at Petroleum Refineries and Chemical Plants (Adopted 1/10/89)
Rule 74.8 Refinery Vacuum Producing Systems, Waste-water Separators and Process Turnarounds (Adopted 7/5/83)
Rule 74.9 Stationary Internal Combustion Engines (Adopted 12/21/93)
Rule 74.10 Components at Crude Oil Production Facilities and Natural Gas Production and Processing Facilities (Adopted 6/16/92)
Rule 74.11 Natural Gas-Fired Residential Water Heaters-Control of NO_x (Adopted 4/9/85)
Rule 74.12 Surface Coating of Metal Parts and Products (Adopted 9/10/96)
Rule 74.15 Boilers, Steam Generators and Process Heaters (5MM BTUs and greater) (Adopted 11/8/94)
Rule 74.15.1 Boilers, Steam Generators and Process Heaters (1–5MM BTUs) (Adopted 6/13/95)
Rule 74.16 Oil Field Drilling Operations (Adopted 1/8/91)
Rule 74.20 Adhesives and Sealants (Adopted 1/14/97)
Rule 74.23 Stationary Gas Turbines (Adopted 3/14/95)
Rule 74.24 Marine Coating Operations (Adopted 9/10/96)
Rule 74.24.1 Pleasure Craft Coating and Commercial Boatyard Operations (Adopted 11/10/98)
Rule 74.26 Crude Oil Storage Tank Degassing Operations (Adopted 11/8/94)
Rule 74.27 Gasoline and ROC Liquid Storage Tank Degassing Operations (Adopted 11/8/94)
Rule 74.28 Asphalt Roofing Operations (Adopted 5/10/94)
Rule 74.30 Wood Products Coatings (Adopted 9/10/96)
Rule 75 Circumvention (Adopted 11/27/78)
Appendix IV-A.—Soap Bubble Tests (Adopted 12/86)

Rule 100 Analytical Methods (Adopted 7/18/72)
Rule 101 Sampling and Testing Facilities (Adopted 5/23/72)
Rule 102 Source Tests (Adopted 11/21/78)
Rule 103 Continuous Monitoring Systems (Adopted 2/9/99)
Rule 154 Stage 1 Episode Actions (Adopted 9/17/91)
Rule 155 Stage 2 Episode Actions (Adopted 9/17/91)
Rule 156 Stage 3 Episode Actions (Adopted 9/17/91)
Rule 158 Source Abatement Plans (Adopted 9/17/91)
Rule 159 Source Abatement Procedures (Adopted 9/17/91)
Rule 220 General Conformity (Adopted 5/9/95)

* * * * *

[FR Doc. 99–21315 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[MO 080–1080b; FRL–6421–5]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Control of Emissions From Hospital/Medical/Infectious Waste Incinerators (HMIWIs); State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the state of Missouri's section 111(d) plan for controlling emissions from existing HMIWIs. The plan was submitted to fulfill the requirements of sections 111 and 129 of the Clean Air Act. The state plan establishes emission limits and controls for sources constructed on or before June 20, 1996.

In the final rules section of the **Federal Register**, EPA is approving the state's submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial action and anticipates no relevant adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to that rule, no further activity is contemplated, and the direct final rule will become effective. If EPA receives relevant 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. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: Comments on this proposed rule must be received in writing by September 20, 1999.

ADDRESSES: Comments may be mailed to Wayne Kaiser, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

FOR FURTHER INFORMATION CONTACT: Wayne Kaiser at (913) 551–7603.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final rule which is located in the rules section of the **Federal Register**.

Dated: August 4, 1999.

William Rice,

Acting Regional Administrator, Region VII.

[FR Doc. 99–21310 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–6419–6]

National Emission Standards for Hazardous Air Pollutants: Halogenated Solvent Cleaning

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This action proposes amendments to the ''National Emission Standards for Hazardous Air Pollutants: Halogenated Solvent Cleaning'' promulgated in the **Federal Register** on December 2, 1994 (59 FR 61801). This action proposes revisions concerning additional compliance options for continuous web cleaning machines, as well as clarifications that apply to steam-heated vapor cleaning machines and to cleaning machines used to clean transformers. Because the proposed revisions ensure that all owners or operators of solvent cleaning machines have appropriate and attainable requirements for their cleaning machines, we do not anticipate receiving adverse comments.

Consequently, these proposed revisions are also being issued as a direct final rule in the ''Final Rules'' section of today's **Federal Register**. If no significant and timely comments are received, no further action will be taken with respect to this proposal and the direct final rule will become final on the date provided in that action.

DATES: Written comments on these proposed changes must be received by September 20, 1999. Anyone requesting a public hearing must contact the EPA no later than August 30, 1999. If a hearing is held, it will take place on September 2, 1999 beginning at 10 a.m. Persons interested in attending the hearing should call Ms. Janet Eck at (919) 541–7946 to verify that a hearing will be held.

ADDRESSES: Written comments should be submitted (in duplicate, if possible) to: Air and Radiation Docket and Information Center (MC–6102), Attention Docket Number A–92–39, Room M–1500, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. The EPA requests that a separate copy of each public comment be sent to the contact person listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: For information concerning the standards and the proposed changes, contact Mr. Paul Almodóvar, Coatings and Consumer Products Group, Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–0283. For information regarding the applicability of this action to a particular entity, contact Ms. Acquanetta Delaney, Manufacturing Branch, Office of Compliance (2223A), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; telephone (202) 564–7061.

SUPPLEMENTARY INFORMATION:

Electronic Comment Submission

Comments may be submitted electronically via electronic mail (E-mail) or on diskette. Electronic comments on this proposed rule may be filed via E-mail at most Federal depository libraries. E-mail submittals should be sent to: ''A-and-R-docket@epamail.epa.gov.'' Electronic comments must be submitted as an American Standard Code for Information Interchange (ASCII) file avoiding the use of special characters or any form of encryption. Comments and data will also be accepted on diskette in WordPerfect, Version 5.1 or 6.1 file format, or ASCII file format. All comments and data for this proposal, whether in paper form or electronic form such as through E-mail or on diskette, must be identified by Docket No. A–92–39. No confidential business information should be submitted through E-Mail.

For additional information, see the direct final rule published in the Final Rules section of today's **Federal Register**.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Continuous web cleaning, Film cleaning, Hazardous substances, Halogenated solvent cleaning machines.

Dated: August 6, 1999.

Carol M. Browner,

Administrator.

[FR Doc. 99–20860 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–6422–6]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of intent to delete Lackawanna Refuse site from the National Priorities List; request for comments.

SUMMARY: The Environmental Protection Agency (EPA) Region III announces its intent to delete the Lackawanna Refuse Superfund Site (Site) 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), as amended. EPA and the Pennsylvania Department of Environmental Protection (PADEP) have determined that all appropriate CERCLA response actions have been implemented and that no further cleanup by responsible parties is appropriate. Moreover, EPA and the Commonwealth have determined that remedial activities conducted at the Site have been protective of public health, welfare, and the environment.

DATES: Comments concerning the proposed deletion of this Site from the NPL may be submitted on or before September 20, 1999.

ADDRESSES: Comments may be submitted to: Ms. Andrea Lord, (3HS21), Project Manager, U.S. Environmental Protection Agency, 1650 Arch Street, Philadelphia, Pennsylvania, 19103 (215) 814–5053.

Comprehensive information on this Site is available for viewing at the Site information repositories at the following locations:

Regional Center for Environmental Information, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, PA 19103 (215) 814–5364; Old Forge Borough Hall, 312 South Main Street, Old Forge, PA 18518.

FOR FURTHER INFORMATION CONTACT: Ms. Andrea Lord (3HS21), U.S. Environmental Protection Agency, Region III, 1650 Arch St., Philadelphia, PA 19103, (215) 814–5053.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. NPL Deletion Criteria
III. Deletion Procedures
IV. Basis of Intended Site Deletion

I. Introduction

The U.S. Environmental Protection Agency, Region III announces its intent to delete the Lackawanna Refuse Superfund Site, Old Forge, Pennsylvania, from the National Priorities List (NPL), appendix B of the National Oil and Hazardous Substance Pollution Contingency Plan (NCP), and requests public comments on this proposed action. EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and maintains the NPL as the list of these sites. EPA and the Commonwealth of Pennsylvania have determined that remedial activities conducted at the Site have been successfully executed.

EPA will accept comments on the proposal to delete this Site for thirty calendar 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 the procedures that EPA is using for this action. Section IV discusses the Lackawanna Refuse Superfund Site and explains how the Site meets the deletion criteria.

II. NPL Deletion Criteria

The NCP establishes the criteria that the Agency uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making this determination, EPA shall consider whether any of the following criteria have been met:

(i) EPA, in consultation with PADEP, has determined that the responsible parties or other parties have implemented all appropriate response actions required; or

(ii) All appropriate Fund-financed responses under CERCLA have been implemented, and EPA, in consultation with PADEP, has determined that no further cleanup by responsible parties is appropriate; or

(iii) The remedial investigation has shown that the release at the Site 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 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. If new information becomes available which indicates a need for further action, EPA may initiate additional remedial actions. Whenever there is a significant release from a deleted site from the NPL, the site may be restored to the NPL without application of the Hazard Ranking System.

In the case of the Lackawanna Refuse Site, EPA has determined that the selected remedy is protective of human health and the environment. Consistent with the State Superfund Contract, between EPA and PADEP, PADEP has agreed to take over operation and maintenance of the Site and conduct an annual inspection. EPA has conducted the first two five-year reviews of the final remedy, and will also perform future five-year reviews.

III. Deletion Procedures

The following procedures were used for the intended deletion of this site:

(i) EPA Region III has recommended deletion and has prepared the relevant documents.

(ii) The Commonwealth of Pennsylvania has concurred with the deletion decision. Concurrent with this National Notice of Intent to Delete, local notice will be published in local newspapers and distributed to appropriate federal, state, and local officials and other interested parties. This local notice presents information on the Site and announces the commencement of the thirty (30) day public comment period on the deletion package.

(iii) The Region has made all relevant documents available for public review in the Regional Office and the local Site information repository.

Deletion of the Site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. The

NPL is designed primarily for informational purposes and to assist Agency management.

Comments received during this Notice and comment period will be evaluated before the final decision to delete. If necessary, the Agency will prepare a Responsiveness Summary to address any significant public comments received.

A deletion will occur 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 Region III.

IV. Basis for Intended Site Deletion

The Lackawanna Refuse Site (Site) is located along a section of the north-south border between Old Forge Borough and Ransom Township, in Lackawanna County, PA. The Site consists of five strip mine pits excavated in the nineteenth century and used in the 1970's as a permitted municipal refuse landfill. The Site is closely bordered by several houses to the east and by the Villa Corporation Trailer Park to the south. Austin Heights, a residential section of Old Forge Borough, is northeast of the Site. The area west of the Site is forested steep hills. Approximately 9000 persons live within one mile of the Site. The local residents do not depend on groundwater as a source of drinking water, but obtain water through a public system derived from reservoirs several miles to the north.

The Site is located above the flood plains of St. Johns Creek and the Lackawanna River. St. Johns Creek, flowing along the lower (eastern) edge of the Site, is an intermittent stream that is a tributary of the Lackawanna River, which flows into the Susquehanna River.

In 1973, a permit was issued by PADEP (then known as the Pennsylvania Department of Environmental Resources) to the Lackawanna Refuse landfill property for the disposal of solid wastes with the condition that a leachate collection system be installed within sixty days. In 1978 the permit was modified by PADER to allow disposal of sludges. Pits 2 and 3 were used for the disposal of municipal refuse, until 1976 when they were filled to capacity and disposal began in Pit 5. All three pits were unlined. Boreholes, air shafts, and rock fractures allowed wastes to migrate via seeps and shallow groundwater from the pits. The leachate collection system was never installed.

In March 1979, PADER issued an order to Lackawanna Refuse suspending the solid waste permit and requiring immediate cessation of the landfill after discovering evidence of the dumping of industrial wastes and pollutants into Pit 5. The order also required Lackawanna Refuse to dig up and dispose of buried drums containing hazardous wastes and all contaminated soil. PADER issued a second order in 1979 requiring Lackawanna Refuse to construct and operate a leachate collection system. Lackawanna Refuse failed to comply with these orders, and the owner was brought to trial in 1982 in the Commonwealth court on criminal charges and subsequently found guilty of illegal dumping.

During pre-trial hearings, operators of trucking firms testified that they brought drums of hazardous waste to the Site and dumped them into Pit 5. Estimates ranged between 10,000–20,000 drums. There were also allegations that radioactive waste was disposed of at the Site in heavy drums that were lined with thick material. Other information included allegations that bulk liquid wastes were disposed of in a depression on the hillside known as the ''borehole pit,'' and that some amount of liquids were sprayed on the site access road for dust control.

In 1980, PADER requested EPA assistance to further excavate and analyze the drums in Pit 5. Seven test areas in Pit 5 were excavated, uncovering 200 drums at depths of five to thirty feet below the surface of the pit. Approximately 90% of the drums were found to be broken or crushed when they were excavated.

Samples were taken from drums containing liquids or sludges and the results showed high concentrations of solvents and paint waste material with high metal and solvent contents. Metals found included cadmium, chromium, copper, lead, and mercury. Organics included benzene, toluene, methylene chloride, carbon tetrachloride, and ethylbenzene. No evidence of the disposal of radioactive waste was observed in these or any subsequent investigations at the Site. A Site investigation by EPA's Environmental Response Team (ERT) in 1982 revealed volatile organic vapors being released from Pit 5. These gases included vinyl chloride, a known carcinogen.

The Site was scored using the Hazard Ranking System (HRS), resulting in an overall score of 36.57. The Site was proposed for the NPL on December 12, 1982, with a final listing on September 8, 1983. EPA prepared a Remedial Action Master Plan (RAMP) in June 1983, and subsequently prepared a Remedial Investigation/Feasibility Study (RI/FS) workplan in August 1983. Work on the RI began the same month and was completed in November 1984. Removal activities were conducted at the Site in September, 1983 when EPA installed a chainlink gate at the beginning of the access road to control vehicular traffic, and a chainlink fence around all three pit areas to prevent unauthorized access to the Site. The Record of Decision (ROD) describing the selected remedy for the Site was signed by the EPA Regional Administrator on March 22, 1985.

The ROD selected the following remedy for the Site: Removal of all drums and highly contaminated municipal refuse from Pit 5 for offsite disposal at a qualifying Resource Conservation and Recovery Act (RCRA) facility; Construction of a clay cap over Pits 2, 3, and 5 that meets RCRA subtitle C requirements; Installation of surface water drainage diversion around all three pits and construction of a leachate collection and treatment system for Pits 2, 3 and 5; Construction of a gas venting system through the caps of all three pits; Removal of the top layer of contaminated soil from the borehole pit for offsite disposal at a qualifying RCRA facility and returning to grade with a soil cover; Removal of the top layer of contaminated soil from the access road and reconstruction of the road with appropriate drainage and sedimentation controls; Removal of dried paint and contaminated soil in the paint spill area for offsite disposal at a qualifying RCRA facility; Development of a monitoring program during the remedial action, which would include monitoring of the existing wells onsite, the gas venting system, and the leachate treatment system; and operation and maintenance (O&M) of the cap and the leachate collection and treatment system to be implemented by the State.

EPA entered into an Interagency Agreement with the U.S. Army Corps of Engineers (USACE) to perform the Remedial Action at the Site. All components of the Remedial Action were constructed with the exception of the leachate treatment plant. EPA and PADEP found the levels of contamination in the leachate to be lower than expected, and in September 1993 EPA issued an Explanation of Significant Differences (ESD) Report which set forth EPA and PADEP's decision not to implement the leachate treatment component of the remedy. From 1989 until 1992, EPA and PADEP monitored Site conditions on a regular basis by checking for leachate ''break outs'; that is, evidence that the level of leachate was building up within the

landfill and ''breaking out'' along the cap perimeter. There were no such breakouts during that time period.

EPA developed a monitoring program during the Remedial Action to monitor the existing groundwater wells onsite and the gas venting system. All drums and highly contaminated solid wastes were removed, and approximately 40,000 cubic yards of contaminated soil were excavated and disposed offsite. The leachate collection system and the synthetic cover were installed in 1989. The final grading and seeding of the Site were completed in 1990.

On May 7, 1991, PADEP commenced operation and maintenance of the Remedial Action at the Site. On March 28, 1994, EPA issued a Final Site Close Out Report. Pursuant to section 121 (c) of CERCLA, 42 U.S.C. 9621 (c) EPA conducted the first five-year review of the Site in 1995 and the report was subsequently issued on September 28, 1995. EPA conducted a second five-year review of the Site in February 1999, and subsequently issued a report on March 5, 1999. Both five-year reviews found the site to be protective of human health and the environment.

The remedy selected for this Site has been implemented in accordance with the Record of Decision. The remedy has resulted in the significant reduction of the long-term potential for release of hazardous substances. Human health threats and potential environmental impacts have been minimized. EPA and PADEP have determined that the remedy implemented at the Site continues to provide adequate protection of human health and the environment.

EPA, with concurrence of the PADEP, believes that the criteria for deletion of this Site have been met. Therefore, EPA is proposing deletion of the Lackawanna Refuse Site from the NPL.

Dated: August 9, 1999.

Thomas Voltaggio,

Acting Regional Administrator, Region III.

[FR Doc. 99–21317 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–6422–8]

National Oil and Hazardous Substances Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency.

ACTION: Notice of intent to delete the release from the Taylor Borough Superfund site from the National Priorities List (NPL) and request for comments.

SUMMARY: The Environmental Protection Agency (EPA) Region III announces its intent to delete the release from the Taylor Borough Site (Site) 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 Substance Pollution Continency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, (CERCLA). EPA and the Commonwealth of Pennsylvania, through the Pennsylvania Department of Environmental Protection (PADEP) 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 20, 1999.

ADDRESSES: Comments may be mailed to Maria de los A. Garcia, (3HS21), Remedial Project Manager, U.S. Environmental Protection Agency, 1650 Arch St., Philadelphia, PA 19103, 215–814–3199, Fax 215–814–3002, e-mail garcia.maria@epa.gov. Comprehensive information on this Site is available through the public docket which is available for viewing at the Site information repositories at the following locations: U.S. EPA Region III, Administrative Records, 1650 Arch St., Philadelphia, PA 19103, 215–566–3157; and the Taylor Borough Municipal Building, 122 Union Street, Taylor, PA 18517.

FOR FURTHER INFORMATION CONTACT: Maria de los A. Garcia (3HS21), U.S. Environmental Protection Agency, 1650 Arch St., Philadelphia, PA 19103, 215–814–3199, Fax 215–814–3002, e-mail garcia.maria@epa.gov.

SUPPLEMENTARY INFORMATION:

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I. Introduction

The U.S. Environmental Protection Agency (EPA) Region III announces its intent to delete the release from the Taylor Borough Site, Taylor Borough, Lackawanna County, Pennsylvania, 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 on the proposed deletion. EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and maintains the NPL as the list of these sites. EPA and the Commonwealth of Pennsylvania have determined that the remedial action for the Site has been successfully executed. EPA will accept comments on the proposal to delete the release from the NPL 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 the procedures that EPA is using for this action. Section IV discusses the Taylor Borough Site and explains how the Site meets the deletion criteria.

II. NPL Deletion Criteria

Section 300.425(e) of the NCP provides that releases may be deleted from, or recategorized on the NPL where no further response is appropriate. In making a determination to delete a release from the NPL, EPA shall consider, in consultation with the state, whether any of the following criteria has been met:

(i) Responsible parties or other persons have implemented all appropriate response actions required;

(ii) All appropriate Fund-financed response under CERCLA has been implemented, and no further response 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 the release 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 this Site, EPA conducted a five year review in March 1993 and a second one in September 1998. Based on these reviews, EPA determined that conditions at the Site remain protective of public health and the environment. As explained below, the Site meets the NCP's deletion criteria listed above. If

new information becomes available which indicates a need for further action, EPA may initiate remedial actions. Whenever there is a significant release from a site deleted from the NPL, the site shall be restored to the NPL without the application of the Hazard Ranking System (HRS).

III. Deletion Procedures

The following procedures were used for the intended deletion of the release from the Site:

(1) All appropriate response under CERCLA has been implemented and no further action by EPA is appropriate; (2) The Pennsylvania Department of Environmental Protection (PADEP) 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 local Site information repositories.

For deletion of the release from the NPL, EPA's Regional Office will accept and evaluate public comments on EPA's Notice of Intent to Delete before making a final decision to delete. If necessary, the Agency will prepare a Responsiveness Summary, responding to each significant comment submitted during the public comment period. Deletion of the release from the NPL does not itself create, alter, or revoke any individual's rights or obligations. The NPL is designed primarily for informational purposes and to assist Agency management. As mentioned in section II of this document, § 300.425(e)(3) of the NCP states that the deletion of a release from a site from the NPL does not preclude eligibility for future response actions.

IV. Basis for Intended Site Deletion

The following site summary provides the Agency's rational for the proposal to delete this release from the NPL.

Site Background and History

The Taylor Borough Site is located in Lackawanna County, Pennsylvania and the entire Site encompasses approximately 125 acres. The Site is a former municipal landfill located in the Lackawanna Valley, which has historically been extensively mined for anthracite coal. A series of underground mines underlie the Taylor Borough Site. Following the mining operations at the Site, the City of Scranton used the unreclaimed strip mine pits as a municipal landfill from approximately 1967 through 1968. Records from PADEP also document the disposal of industrial wastes. After the landfill operations ceased, drummed industrial wastes were found on the surface of the Site. Beginning in 1981, EPA Region III and PADEP conducted field inspections of the Site. The majority of the surface drums were concentrated in six areas of the Site. Most drums were open and the contents may have spilled during the dumping. Many had also been punctured by bullet holes. Air sampling close to the drums identified the presence of volatile organic compounds (VOCs). Drum and drum spill samples were analyzed in 1982 and were found to contain benzene, toluene, and other substituted benzene, phthalate acid esters, polynuclear aromatic hydrocarbons (PAHs), tricholoroethene (TCE), chloroform, and other organic chemicals. In 1983, a fire occurred on the surface of the landfill. It is believed that mine spoil was pushed over burning areas to extinguish the fire. As a result, some drums were partially buried. Because the fire had engulfed several drums, EPA instituted an Emergency Removal Action under Section 104 of CERCLA. From September through November of 1983, 1,141 drums were removed from the Site. In 1983, the Site was placed on the National Priorities List (NPL) and authorization to proceed with a Remedial Investigation/ Feasibility Study (RI/FS) was approved that same year. In 1986 the RI/FS was completed. Records of Decision (RODs) for soil and ground water were signed in 1985 and in 1986, respectively. The selected remedial action in the 1985 ROD included the following activities: removal and off-site disposal at a qualified facility of approximately 125 crushed and intact drums and remnants that remained on the site surface or partially buried; collection and treatment of contaminated surface water in on-site Ponds 1 and 2, located adjacent to Drum Storage Areas 1 and 2; excavation of contaminated soils and waste from former Drum Storage Areas 1 and 2 and sediments in Ponds 1 and 2 for off-site disposal to a qualified RCRA facility; proper backfilling and placement of a 24-inch soil cover over the former Drum Storage Areas 3 and 6, all of the area between them, and the former Drum Storage Area 4; installation of a chain-link fence around the perimeter of both soil-covered areas. The selection of remedial activities for ground water was deferred in the June 1985 ROD until ground water was further assessed. In March 1986, the EPA issued a ROD concerning ground water. It selected no remedial action for ground water, but required ground water monitoring.

Response Actions

In 1987, a Consent Decree was signed between the United States and five potentially responsible parties (PRPs). A Remedial Design for the specific remedial actions, approved by EPA and the Commonwealth of Pennsylvania, was an exhibit to the Consent Decree. Construction activities were initiated in July 1987. Remedial activities included the solidification of sediments from two ponds (Ponds 1 and 2). The sediments from these two ponds were mixed with kiln dust for solidification and the solidified sediments were compacted in place. Final design contours were achieved by the placement of clean fill over this solidified material. Approximately 10 intact drums containing solvents were uncovered during the excavation of contaminated soils and wastes from former Drum Storage Areas 1 and 2. Those 10 drums along with scattered surface drum remnants and approximately 5,000 cubic yards of excavated soil and waste material were removed and disposed of off-site. Also, a minimum two-foot soil cover was placed on the former Drum Storage Areas 3 and 6 and the entire area in between. In addition, a two-foot soil cover was placed on the former Drum Storage Area 4. A six-foot chainlink fence (1 mile in length) was installed with two locking gates prior to the excavation in Drum Storage Areas 1 and 2. The fence completely encompasses the remediated areas. Construction activities were concluded in May 1988.

Operations and Maintenance

The 1985 and 1986 RODs for the Site required that post-remediation operation and maintenance (O&M) activities be conducted by EPA Region III, including ground water and surface water monitoring through a sampling program, and maintenance of the soil cover. Surface and sediments in St. Johns Creek as well as a specific list of monitoring wells, were to be sampled for at least five years. Regular maintenance activities have been conducted at the Site and the sampling required in the RODs was completed in 1996.

Five-Year Review

CERCLA requires a five-year review of all sites with hazardous substances remaining above the health-based levels for unrestricted use of the site. Since hazardous materials remain at the Site,

the five-year review process will be used to insure that the soil cover is still intact. EPA issued a five-year review report in 1993 and another one in 1998, where it evaluated the results of the maintenance and monitoring activities at the Site. These reports concluded that the Taylor Borough Site is protective of human health and the environment. Specifically, the 1998 five-year review recommended to continue operation and maintenance activities at the Site. These activities include: annual vegetative maintenance, drainage control repair, and maintenance of the soil cap drainage structures, monitoring wells, and other Site structures. In addition, this five-year review recommended ground water monitoring activities for 5 years to assess the continued effectiveness of the remedial action.

Applicable Deletion Criteria

The remedy selected for this Site has been implemented in accordance with the Records of Decision. Therefore, no further response action is necessary. The remedy has resulted in the significant reduction of the long-term potential for release of contaminants, therefore, human health and potential environmental impacts have been minimized. EPA and the Commonwealth of Pennsylvania find that the remedies implemented continue to provide adequate protection of human health and the environment.

Dated: August 9, 1999.

W. Michael McCabe,

Regional Administrator, Region 3.

[FR Doc. 99–21316 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 64, No. 160
Thursday, August 19, 1999

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Advisory Committee on Agricultural Biotechnology

AGENCY: Research, Education, and Economics, USDA.

ACTION: Notice of intent to establish; request for nominations and comments.

SUMMARY: The U.S. Department of Agriculture proposes to establish the Advisory Committee on Agricultural Biotechnology (ACAB). The Secretary of Agriculture is requesting nominations for qualified persons to serve as members of the ACAB.

DATES: Written nominations must be received on or before September 3, 1999.

ADDRESSES: Nominations should be sent to Michael Schechtman, Designated Federal Official, Office of the Deputy Secretary, USDA, 202B Jamie L. Whitten Federal Building, 14th and Independence Avenue, SW, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Michael Schechtman, Designated Federal Official, telephone (202) 720–3817; fax (202) 690–4265; email michael.g.schechtman@usda.gov. To obtain form AD–755 ONLY please contact Dianne Harmon, Office of Pest Management Policy, telephone (202) 720–4074, fax (202) 720–3191; email *dharmon@ars.usda.gov*.

SUPPLEMENTARY INFORMATION:

Advisory Committee Purpose

The Secretary of Agriculture is establishing the Advisory Committee on Agricultural Biotechnology (ACAB) to advise the Secretary of Agriculture on the broad array of issues related to the expanding dimensions and importance of agricultural biotechnology. USDA encourages and supports the responsible development and utilization of beneficial new agricultural products, including those produced through biotechnology, and assures the safety of new products with a science based regulatory approach. USDA has complex and crucial roles in protecting public health and safety, the natural environment, and a competitive, vibrant, and diverse farm economy; ensuring the quality and availability of our food and fiber supply; and maintaining the competitive position of American agricultural products in the international marketplace. These topics are of critical concern in the conduct of agricultural biotechnology research, regulation, and commercialization. Some of the topics that the Secretary of Agriculture has identified for the ACAB's initial consideration include: effects of industry concentration and consolidation on farmers; intellectual property rights and grower autonomy; effects of biotechnology on small farmers; ways to maximize or encourage potential benefits of biotechnology in different agricultural sectors; and USDA's role in assuring that farmers have an array of choices for future agricultural technology and practices. The ACAB will meet in Washington, DC, up to four (4) times per year.

Task Force Membership

The ACAB will be made up of United States citizens. It will consist of 25 members of whom no more than five (5) will be federal employees. Members of ACAB should have recognized expertise in one or more of the following areas: recombinant-DNA (rDNA) research and applications using plants; rDNA research and applications using animals; rDNA research and applications using microbes; food science; silviculture and related forest science; fisheries science; ecology; veterinary medicine; the broad range of farming or agricultural practices; weed science; plant pathology; small farm advocacy; biodiversity issues; applicable laws and regulations relevant to agricultural biotechnology policy; risk assessment; consumer advocacy and public attitudes; public health/epidemiology; occupational health; ethics, including bioethics; human medicine; biotechnology industry activities and structure; intellectual property rights systems; and international trade. Members will be selected by the Secretary of Agriculture in order to achieve a balanced representation of viewpoints to address effectively USDA biotechnology policy issues under consideration.

Nominations for ACAB membership must be in writing and provide the appropriate background documents required by USDA policy, including background disclosure form AD–755. Neither the form nor the information it contains may be released to the public, except under an order issued by a Federal court or as otherwise provided under the Privacy Act (5 U.S.C. 552a).

No member may serve on the ACAB for more than three (3) consecutive terms. Nominees will initially serve for terms of 1 or 2 years for purposes of continuity.

Members of the ACAB and its subcommittees shall serve without pay, but with reimbursement of travel expenses and per diem for attendance at ACAB and subcommittee functions for those ACAB members who require assistance in order to attend the meetings. While away from home or their regular place of business, those members will be eligible for travel expenses paid by REE, USDA, including per diem in lieu of subsistence, at the same rate as a person employed intermittently in the government service is allowed under Section 5703 of Title 5, United States code.

Submitting Nominations

Nominations should be typed and include the following:

1. A brief summary of no more than two (2) pages explaining the nominees suitability to serve on the ACAB.
2. A resume or curriculum vitae.
3. A completed copy of form AD–755.

Nominations should be sent to Michael Schechtman at the address listed above, and be post marked no later than September 3, 1999.

USDA is actively soliciting nominations of qualified minorities, women, persons with disabilities and members of low income populations through outreach to minority-focused media outlets, Historically Black Colleges and Universities, including Clark Atlanta University, the Hispanic Association of Colleges and Universities, the National Congress of Native American Indians, the Intertribal Agriculture Council, Gallaudet and Purdue Universities, and the Rural Coalition. To ensure that recommendations of the ACAB take into account the needs of under-served and

diverse communities served by the USDA, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

Dated: August 12, 1999.

I.M. Gonzalez,

Under Secretary for Research, Education, and Economics.

[FR Doc. 99–21477 Filed 8–18–99; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–822, A–122–823]

Certain Corrosion-Resistant Carbon Steel Flat Products and Certain Cut-to-Length Carbon Steel Plate From Canada: Preliminary Results of Antidumping Duty Administrative Reviews, Intent To Revoke in Part, Intent Not to Revoke in Part, and Rescission of Review in Part

AGENCY: Import Administration, International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of preliminary results of the antidumping duty administrative review, intent to revoke in part, intent not to revoke in part, and rescission of review in part.

SUMMARY: In response to requests from interested parties, the Department of Commerce (the Department) is conducting administrative reviews of the antidumping duty orders on certain corrosion-resistant carbon steel flat products and certain cut-to-length carbon steel plate from Canada. These reviews cover four manufacturers/exporters of corrosion resistant steel and two manufacturers/exporters of cut-to-length steel plate (one respondent manufactured both products), and the period August 1, 1997 through July 31, 1998.

We have preliminarily determined that sales have been made below normal value (''NV'') by various companies subject to these reviews. See ''Preliminary Results of Reviews'' section below for the company-specific rates. If these preliminary results are adopted in our final results of these administrative reviews, we will instruct the U.S. Customs Service to assess antidumping duties based on the difference between the export price (''EP'') or constructed export price (''CEP'') and the NV.

EFFECTIVE DATE: August 19, 1999.

FOR FURTHER INFORMATION CONTACT: Gideon Katz at (202) 482–4255 (Dofasco Inc. and Sorevco Inc. (collectively, ''Dofasco'')), Sarah Ellerman at (202) 482–4106 (Continuous Colour Coat (''CCC'')), Mark Hoadley at (202) 482–0666 (Gerdau MRM Steel (''MRM''), National Steel Co. (''National''), and Algoma Steel Co. (''Algoma'')), Elfi Blum at (202) 482–0197 (Stelco, Inc.(''Stelco'')), or Maureen Flannery at (202) 482–3020, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act), are to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are to 19 CFR part 351 (April 1998).

Background

On August 19, 1993, the Department published in the **Federal Register** (58 FR 44162) the antidumping duty orders on certain corrosion-resistant carbon steel flat products and certain cut-to-length carbon steel plate from Canada. On August 21, 1998, MRM requested a review of its exports of cut-to-length steel plate and requested that the Department revoke the order on cut-to-length steel plate as it pertains to MRM. On August 31, 1998, Stelco requested a review of its exports of cut-to-length steel plate and that the Department revoke the order on cut-to-length steel plate as it pertains to Stelco. On August 31, 1998, National, Dofasco, Stelco, and CCC requested a review of their exports of corrosion-resistant steel, and Algoma requested a review of its exports of cut-to-length carbon steel plate.

On August 31, 1998, Bethlehem Steel Corporation, U.S. Steel Group (a unit of USX Corporation), Inland Steel Industries, Inc., Gulf States Steel Inc. of Alabama, Sharon Steel Corporation, Geneva Steel, and Lukens Steel Company, petitioners, requested reviews of Algoma and Stelco exports of cut-to-length carbon steel plate.

On August 31, 1998, Bethlehem Steel Corporation, U.S. Steel Group, Inland Steel Industries, Inc., AK Steel Corporation, LTV Steel Co., Inc., and National Steel Corporation, petitioners, requested reviews of CCC, Dofasco, and Stelco exports of corrosion-resistant carbon steel flat products.

On September 29, 1998, in accordance with section 751 of the Act, we published a notice of initiation of administrative reviews of these orders for the period August 1, 1997 through July 31, 1998 (62 FR 50292).

Under section 751(a)(3)(A) of the Act, the Department may extend the deadline for completion of an administrative review if it determines that it is not practicable to complete the review within the statutory time limit of 365 days. On February 26, 1999, the Department published a notice of extension of the time limit for the preliminary results in the review to July 30, 1999. *See Corrosion-Resistant Carbon Steel Flat Products and Cut-to-Length Carbon Steel Plate: Extension of Time Limits for Preliminary Results of Antidumping Administrative Review,* 64 FR 9475.

On July 30, 1999, the Department published a second notice of extension of the time limit for the preliminary results in the review from July 30, 1999 to August 6, 1999. *See Certain Corrosion-Resistant Carbon Steel Flat Products and Certain Cut-to-Length Carbon Steel Plate From Canada: Extension of Time Limits for Preliminary Results of Antidumping Administrative Review,* 64 FR 42338.

On August 6, 1999 the Department extended the time limits for the Preliminary Results in the review to August 16, 1999. *See Certain Corrosion-Resistant Carbon Steel Flat Products and Certain Cut-to-Length Carbon Steel Plate From Canada: Extension of Time Limits for Preliminary Results of Antidumping Administrative Review,* 64 FR 43984.

The Department is conducting these reviews in accordance with section 751(a) of the Act.

Scope of Reviews

The products covered by these administrative reviews constitute two separate ''classes or kinds'' of merchandise: (1) certain corrosion-resistant carbon steel flat products, and (2) certain cut-to-length carbon steel plate.

The first class or kind, certain corrosion-resistant steel, includes flat-rolled carbon steel products, of rectangular shape, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished or coated with plastics or other nonmetallic substances in addition to the metallic coating, in coils (whether or not in successively superimposed layers) and of a width of 0.5 inch or greater, or in straight lengths

which, if of a thickness less than 4.75 millimeters, are of a width of 0.5 inch or greater and which measures at least 10 times the thickness or if of a thickness of 4.75 millimeters or more are of a width which exceeds 150 millimeters and measures at least twice the thickness, as currently classifiable in the Harmonized Tariff Schedule (HTS) under item numbers 7210.30.0030, 7210.30.0060, 7210.41.0000, 7210.49.0030, 7210.49.0090, 7210.61.0000, 7210.69.0000, 7210.70.6030, 7210.70.6060, 7210.70.6090, 7210.90.1000, 7210.90.6000, 7210.90.9000, 7212.20.0000, 7212.30.1030, 7212.30.1090, 7212.30.3000, 7212.30.5000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7212.60.0000, 7215.90.1000, 7215.90.3000, 7215.90.5000, 7217.20.1500, 7217.30.1530, 7217.30.1560, 7217.90.1000, 7217.90.5030, 7217.90.5060, and 7217.90.5090. Included in this review are corrosion-resistant flat-rolled products of non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process (i.e., products which have been ''worked after rolling'')—for example, products which have been beveled or rounded at the edges. Excluded from this review are flat-rolled steel products either plated or coated with tin, lead, chromium, chromium oxides, both tin and lead (''terne plate''), or both chromium and chromium oxides (''tin-free steel''), whether or not painted, varnished or coated with plastics or other nonmetallic substances in addition to the metallic coating. Also excluded from this review are clad products in straight lengths of 0.1875 inch or more in composite thickness and of a width which exceeds 150 millimeters and measures at least twice the thickness. Also excluded from this review are certain clad stainless flat-rolled products, which are three-layered corrosion-resistant carbon steel flat-rolled products less than 4.75 millimeters in composite thickness that consist of a carbon steel flat-rolled product clad on both sides with stainless steel in a 20%–60%–20% ratio.

The second class or kind, certain cut-to-length plate, includes hot-rolled carbon steel universal mill plates (i.e., flat-rolled products rolled on four faces or in a closed box pass, of a width exceeding 150 millimeters but not exceeding 1,250 millimeters and of a thickness of not less than 4 millimeters, not in coils and without patterns in relief), of rectangular shape, neither clad, plated nor coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances; and certain hot-rolled carbon steel flat-rolled products in straight lengths, of rectangular shape, hot rolled, neither clad, plated, nor coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances, 4.75 millimeters or more in thickness and of a width which exceeds 150 millimeters and measures at least twice the thickness, as currently classifiable in the HTS under item numbers 7208.40.3030, 7208.40.3060, 7208.51.0030, 7208.51.0045, 7208.51.0060, 7208.52.0000, 7208.53.0000, 7208.90.0000, 7210.70.3000, 7210.90.9000, 7211.13.0000, 7211.14.0030, 7211.14.0045, 7211.90.0000, 7212.40.1000, 7212.40.5000, and 7212.50.0000. Included in this review are flat-rolled products of non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process (*i.e.*, products which have been ''worked after rolling'')—for example, products which have been beveled or rounded at the edges. Excluded from this review is grade X–70 plate. Also excluded is cut-to-length carbon steel plate meeting the following criteria: (1) 100% dry steel plates, virgin steel, no scrap content (free of Cobalt-60 and other radioactive nuclides); (2) .290 inches maximum thickness, plus 0.0, minus .030 inches; (3) 48.00 inch wide, plus .05, minus 0.0 inches; (4) 10 foot lengths, plus 0.5, minus 0.0 inches; (5) flatness, plus/minus 0.5 inch over 10 feet; (6) AISI 1006; (7) tension leveled; (8) pickled and oiled; and (9) carbon content, 0.03 to 0.08 (maximum).

With respect to both classes or kinds, the HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive of the scope of these reviews.

Verification

As provided in section 782(i) of the Act, we verified information provided by MRM (cost and sales), Dofasco (cost and sales), and Stelco (sales for plate, cost for both corrosion-resistant and plate) using standard verification procedures, including on-site inspections of the manufacturers' facilities and the examination of relevant sales and financial records. Our verification results are outlined in public versions of the verification reports on file with the Central Records Unit, in room B–099 of the Herbert C. Hoover Building.

Product Comparisons

In accordance with section 771(16) of the Act, we considered all products produced by the respondents that are covered by the description in the Scope of Reviews section above and sold in the home market during the period of review (POR) to be foreign like products 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 Appendix V of the Department's September 19, 1998 antidumping questionnaires.

Fair Value Comparisons

To determine whether sales of subject merchandise to the United States were made at less than fair value, we compared the EP or the CEP to NV, as described in the ''United States Price'' and ''Normal Value'' sections of this notice. In accordance with section 777A(d)(2) of the Act, we calculated monthly weighted-average prices for NV and compared these to individual U.S. transaction prices.

Rescission of Review for Algoma

In *Certain Corrosion-Resistant Carbon Steel Flat Products and Certain Cut-to-Length Carbon Steel Plate from Canada: Final Results of Antidumping Duty Administrative Reviews and Determination to Revoke in Part*, 64 FR 2173 (January 13, 1999) (*''Canadian Steel 4th''*), the Department revoked the order on cut-to-length steel plate as it pertains to Algoma. Before the Department's determination had been finalized, however, we had already initiated our review, at the request of both Algoma and petitioners, of Algoma's exports of cut-to-length plate to the United States for the period August 1, 1997 through July 31, 1998. We now rescind this review insofar as it pertains to Algoma.

Intent To Revoke (MRM) and Intent Not to Revoke (Stelco)

On August 31, 1998, and August 21, 1998, respectively, Stelco and MRM submitted requests, in accordance with 19 CFR 351.222(b), that the Department revoke the order covering cut-to-length carbon steel plate from Canada with respect to their sales of this merchandise.

In accordance with 19 CFR 351.222(b)(2)(iii), these requests were accompanied by certifications from Stelco and MRM that they had not sold the subject merchandise at less than NV for a three-year period, including this

review period, and would not do so in the future. The Department conducted verifications of Stelco's and of MRM's responses for this period of review.

Prior to considering whether it is appropriate to revoke an order pursuant to 19 CFR 351.222(b)(2), the Department ''must be satisfied that, *during each of the three (or five) years*, there were exports to the United States *in commercial quantities* of the subject merchandise to which a revocation or termination will apply.'' 19 CFR 351.222(d)(1) (emphasis added). In other words, the Department must be satisfied that the company participated meaningfully in the U.S. market during each of the three years at issue, and that past margins are reflective of a company's normal commercial activity. *See Canadian Steel 4th; see also Pure Magnesium from Canada: Preliminary Results of Antidumping Administrative Review and Notice of Intent Not To Revoke Order in Part*, 63 FR 26147 (May 12, 1998).

Based on the current record, we preliminarily find that Stelco did not sell merchandise in the United States in commercial quantities during the current administrative review (one of the three consecutive review periods cited by Stelco to support its request for revocation). Stelco made only a few sales totaling 47 tons [1] of subject merchandise in the United States during the POR. By contrast, during the period covered by the antidumping investigation, which was only six months long, Stelco made several thousand sales totaling approximately 30,000 tons.[2] In other words, Stelco's sales for the *entire year* of the current POR amount to only 0.173 percent of its sales volume during the *six months* covered by the investigation. Similarly, during the previous POR Stelco sold approximately 2,000 tons of subject merchandise in the United States. While this amount is small in comparison to the amount sold prior to issuance of the order, it is over 40 times greater than the amount sold during the period covered by the current administrative review.

Because of our preliminary finding that, in the instant period of review, Stelco did not sell subject merchandise in the United States in commercial quantities, we preliminarily determine that Stelco does not qualify for revocation from the order on steel plate under sections 351.222 (b) and (d)(1).

We preliminarily determine that MRM's aggregate sales were made in commercial quantities over the course of its three consecutive review periods of zero margins. *See Memorandum to the File: Analysis Memorandum for the Preliminary Results of Review for MRM* (August 12, 1999). Thus, we preliminarily determine that MRM qualifies for a review of whether the order on steel plate should be revoked as to sales of its products.

Pursuant to 19 CFR 351.222(b)(2), in determining whether to revoke an antidumping order in part, (1) we must conclude that the company has sold subject merchandise at not less than normal value to the United States for three consecutive review periods, (2) we must conclude that it is not likely that the companies eligible for revocation will in the future sell the subject merchandise at less than NV, and (3) the company must agree to the immediate reinstatement of the order if the Department concludes that the company, subsequent to the revocation, has sold the subject merchandise at less than NV.

MRM has satisfied the three prongs of 19 CFR 351.222(b)(2). In the two prior reviews of this order, we determined that MRM sold cut-to-length carbon steel plate from Canada at not less than NV. As discussed in detail below, we preliminarily determine that MRM sold cut-to-length carbon steel plate at not less than NV during this review period.

Moreover, the Department's policy in the past has been that, in the absence of evidence to the contrary, three consecutive review periods with no dumping margins is evidence that it is not likely that a company eligible for revocation will in the future sell the subject merchandise at less than NV. *See Dynamic Random Access Memory Semiconductors of One Megabyte or Above From the Republic of Korea, Notice of Final Results of Antidumping Duty Administrative Review and Determination Not To Revoke Order In Part*, 62 FR 39809, 39810 (July 24, 1997). There is no evidence on the record, other than MRM's history of zero margins over the past three review periods, indicating MRM's likelihood to sell at less than NV in the future.

Finally, MRM agreed to the order's immediate reinstatement as it pertains to its sales, as long as any firm is subject to the order, if the Department concludes under 19 CFR 351.216 that, subsequent to revocation, it has sold the subject merchandise at less than NV. Since we preliminarily conclude that all criteria for revocation have been satisfied, we intend to revoke the order as to MRM.

Duty Absorption

On October 28, 1998, the petitioners requested that the Department determine whether antidumping duties had been absorbed during the POR for corrosion-resistant steel for Dofasco, CCC, and Stelco, and for cut-to-length plate for MRM and Stelco. Section 751(a)(4) of the Act provides for the Department, if requested, to determine during an administrative review initiated two or four years after publication of the order, whether antidumping duties have been absorbed by a foreign producer or exporter, if the subject merchandise is sold in the United States through an affiliated importer. In this case, Dofasco, CCC, MRM, and Stelco sold to the United States through an affiliated importer.

Section 351.213(j)(2) of the Department's regulations provides that for transition orders (i.e., orders in effect on January 1, 1995), the Department will conduct duty absorption reviews, if requested, for administrative reviews initiated in 1996 or 1998. Because the order underlying this review was issued prior to January 1, 1995, and this review was initiated in 1998, we will make a duty absorption determination in this segment of the proceeding.

We have preliminarily determined that there is no dumping margin on any of MRM's and Stelco's U.S. sales of cut-to-length plate during the POR. Therefore, we preliminarily find that antidumping duties have not been absorbed by MRM and Stelco on their U.S. sales of cut-to-length plate.

We have preliminarily determined that there is a *de minimis* margin on Dofasco's U.S. sales of corrosion-resistant steel during the POR. Therefore, we preliminarily find that antidumping duties have not been absorbed by Dofasco on its U.S. sales of corrosion-resistant steel. Also for corrosion-resistant steel, there is no evidence on the record that unaffiliated purchasers of subject merchandise sold by CCC and Stelco will ultimately pay the antidumping duties to be assessed on entries during the review period. Accordingly, based on the record, we cannot conclude that the unaffiliated purchasers in the United States will pay the ultimately assessed duty. Therefore, we preliminarily find that for CCC's and Stelco's sales of corrosion-resistant steel, antidumping duties have been absorbed by the producer or exporter during the POR. We will request that all the above companies place on the record evidence that unaffiliated

[1] Stelco's response (public version) to Section A of the Department's questionnaire in the current administrative review of cut-to-length carbon steel products from Canada (Oct. 26, 1998) at Exhibit A–1.

[2] Stelco's response (public version) to Section A of the Department's questionnaire in the antidumping duty investigations of certain flat carbon steel (cut-to-length plate) products from Canada (Sep. 11, 1992) at Exhibit 1.

purchasers will ultimately pay the antidumping duties to be assessed on entries during the review period for the respective class or kind of merchandise.

United States Price

For United States price, we used EP when the subject merchandise was sold directly or indirectly to the first unaffiliated purchaser in the United States prior to importation and CEP was not otherwise warranted by facts on the record.

CCC

The Department calculated EP for CCC based on packed, prepaid or delivered prices to customers in the United States. We made deductions from the starting price, net of discounts and price adjustments, for movement expenses (foreign and U.S. freight, brokerage and handling, and U.S. Customs duties), in accordance with section 772(c)(2) of the Act.

We have determined to treat certain payments, which CCC reported as ''credit notes,'' as price adjustments which should be excluded from the starting price. *See Memorandum to the File: Analysis Memorandum for the Preliminary Results of Review for CCC* (August 12, 1999).

It is the Department's standard practice to use the invoice date as the date of sale; we may, however, use a date other than the invoice date if we are satisfied that a different date better reflects the date on which the exporter or producer establishes the material terms of sale. *See* 19 CFR 351.401(i). Our questionnaire instructed CCC to report the date of invoice as the date of sale; it also stated, however, that for EP sales ''(t)he date of sale cannot occur after the date of shipment.'' Therefore, we used date of invoice as date of sale, but, in some instances, when shipment date preceded invoice date, we used the date of shipment.

Dofasco

For purposes of these reviews, we treated Dofasco, Inc. and Sorevco, Inc. as one respondent, as we have done in prior segments of the proceeding. *See, e.g., Certain Corrosion-Resistant Carbon Steel Flat Products from Canada: Final Determination of Sales at Less than Fair Value,* 58 FR 37099 (1993), and *Canadian Steel 4th.*

The Department calculated EP for Dofasco based on packed, prepaid or delivered prices to customers in the United States. We made deductions from the starting price, net of discounts and rebates, for movement expenses (foreign and U.S. movement, and post-sale warehousing) in accordance with section 772(c)(2) of the Act. As discussed in prior reviews, certain Dofasco sales have undergone minor further processing in the United States as a condition of sale to the customer. *See Certain Corrosion-Resistant Carbon Steel Flat Products and Certain Cut-to-Length Carbon Steel Plate From Canada: Final Results of Antidumping Duty Administrative Reviews,* 62 FR 18461 (April 15, 1997). In order to determine the value of subject merchandise at the time of exportation of such merchandise to the United States, the Department has deducted the price charged to Dofasco for this minor further processing from gross unit price to determine U.S. price.

It is the Department's current practice normally to use the invoice date as the date of sale; we may, however, use a date other than the invoice date if we are satisfied that a different date better reflects the date on which the exporter or producer establishes the material terms of sale. *See* 19 CFR 351.401(i) (62 FR at 27411). Our questionnaire instructed Dofasco to report the date of invoice as the date of sale; it also stated, however, for EP sales, that ''(t)he date of sale cannot occur after the date of shipment.'' In this review, Dofasco's date of shipment in many instances preceded the date of invoice, and therefore we cannot use the date of invoice as the regulations prescribe. Accordingly, as provided for in 19 CFR 351.401(i) of the regulations, we used the dates of sale described below. These sale dates reflect the dates on which the exporter or producer established the material terms of sale. We used the date of order acknowledgment as date of sale, as reported by Dofasco for all Dofasco sales in both the U.S. market and the home market, except for sales made pursuant to long-term contracts. For Dofasco's sales made pursuant to long-term contracts, we used date of the contract as date of sale. In the rare instance of a rush order, we used the date of shipment as date of sale if a coil was shipped before it was acknowledged. We also used shipment date for sales of secondary products for which there is no order acknowledgment. If there was a change in price, we used the date of Dofasco's order reacknowledgement as date of sale.

We used the date of order confirmation as the date of sale, as reported by Sorevco Inc. (''Sorevco'') for its sales in the home market, except when Sorevco shipped more merchandise than the customer originally ordered, and such overages were in excess of accepted industry tolerances. For those sales we used date of shipment as date of sale.

MRM

The Department calculated EP for MRM based on packed, prepaid or delivered prices to customers in the United States. We made deductions from the starting price for movement expenses (foreign and U.S. movement, brokerage and handling, and U.S. Customs duties) and U.S. selling commissions pursuant to section 772(c)(2) of the Act.

In accordance with standard Department practice, we used date of invoice as date of sale for MRM's U.S. and home market sales. *See* 19 CFR 351.401(i).

National

The Department calculated CEP (there were no EP sales) for National based on packed, prepaid or delivered prices to customers in the United States.[3] We made deductions from the starting price, net of discounts and billing adjustments, for movement expenses (foreign and U.S. freight, warehousing, insurance, brokerage and handling, and U.S. Customs duties), pursuant to section 772(c)(2) of the Act.

National sold goods in the United States with and without U.S. further manufacturing. Where appropriate, the Department reduced CEP by National's costs of further manufacturing its goods in the United States, in accordance with section 772(d)(2).

In accordance with section 772(d)(1) of the Act, we further reduced CEP by direct selling expenses (credit, warranty, and technical service expenses), indirect selling expenses, and inventory carrying costs. Finally, we made an adjustment for an amount of profit allocated to selling expenses incurred in the United States, in accordance with section 772(d)(3) of the Act.

In this review period, National's date of shipment always either was the same as or preceded the date of invoice, and, therefore, we have chosen to use date of shipment as date of sale.

Stelco

Corrosion-resistant steel: We calculated EP based on the packed, prepaid or delivered prices to unaffiliated purchasers in the United States. We made deductions from the starting price for movement expenses, including foreign and U.S. freight,

[3] National, a U.S.-based corporation, ships steel flat products to the United States through its partially owned Canadian subsidiary, DNN Galvanizing Corp (''DNN''). DNN, under a tolling agreement, galvanizes National's steel flat products, which leads to their categorization as subject merchandise. National, however, provided U.S. selling functions for these products, and thus, we considered them to be CEP sales.

brokerage and handling, and U.S. Customs duties, and for discounts and rebates, in accordance with section 772(c)(2) of the Act.

Plate: We calculated EP based on the packed, prepaid or delivered prices to unaffiliated purchasers in the United States. We made deductions for movement expenses, including foreign and U.S. freight, brokerage and handling, and U.S. Customs duties, in accordance with section 772(c)(2) of the Act.

In accordance with standard Department practice, we used date of invoice as date of sale for both corrosion-resistant steel and cut-to-length plate for Stelco's U.S. and home market sales. Only in the event where shipment date was before invoice date did we use the date of shipment.

Normal Value

The Department determines the viability of the home market as the comparison market by comparing the aggregate quantity of home market and U.S. sales. We found that each company's quantity of sales in its home market exceeded five percent of its sales to the United States for the relevant class or kind of merchandise. We, therefore, have determined that each company's home market sales are viable for purposes of comparison with sales of the subject merchandise to the United States, pursuant to section 773(a)(1)(C) of the Act. Moreover, there is no evidence on the record supporting a particular market situation in the exporting companies' country that would not permit a proper comparison of home market and U.S. prices. Therefore, in accordance with section 773(a)(1)(B)(i) of the Act, we based NV on the price at which the foreign like product was first sold for consumption in the home market, in the usual commercial quantities and in the ordinary course of trade and, to the extent practicable, at the same level of trade as the EP or CEP sale.

In accordance with section 773(a)(4) of the Act, except for National, we used CV as the basis for NV when there were no above-cost contemporaneous sales of identical or similar merchandise in the comparison market. We calculated CV in accordance with section 773(e) of the Act. We included the cost of materials and fabrication, selling, general and administrative expenses (SG&A), and profit. In accordance with section 773(e)(2)(A) of the Act, we based SG&A expenses and profit on the amounts incurred and realized by the respondents in connection with the production and sale of the foreign like product in the ordinary course of trade for consumption in the foreign country. For selling expenses, we used the weighted-average home market selling expenses.

We used sales to affiliated customers only where we determined such sales were made at arm's-length prices, *i.e.*, at prices comparable to the prices at which the respondents sold identical merchandise to unaffiliated customers.

For both classes or kinds of merchandise under review and for all respondents (except National), the Department disregarded sales below cost of production (''COP'') in the last completed review. *See Canadian Steel 4th*. We therefore have reasonable grounds to believe or suspect, pursuant to section 773(b)(2)(A)(ii) of the Act, that sales of the foreign like product under consideration for the determination of NV in this review may have been made at prices below COP. Pursuant to section 773(b)(1) of the Act, we initiated COP investigations of sales in the home market by all respondents, except National.

We compared sales of the foreign like product in the home market with model-specific cost of production figures for the POR. In accordance with section 773(b)(3) of the Act, we calculated COP based on the sum of the costs of materials and fabrication employed in producing the foreign like product plus SG&A expenses and all costs and expenses incidental to placing the foreign like product in packed condition and ready for shipment. In our sales-below-cost analysis, we used home market sales and COP information provided by each respondent in its questionnaire responses. We made adjustments where warranted based on our findings at verification.

After calculating COP, we tested whether home market sales of foreign like merchandise were made at prices below COP and, if so, whether the below-cost sales were made within an extended period of time in substantial quantities and at prices that did not permit recovery of all costs within a reasonable period of time. Because each individual price was compared against the POR-long average COP, any sales that were below cost were also not at prices which permitted cost recovery within a reasonable period of time. Model-specific COPs were compared to reported home market prices less any applicable movement charges, discounts, and rebates.

Pursuant to section 773(b)(2)(C) of the Act, where less than 20 percent of a respondent's sales of a given model were at prices less than COP, we did not disregard any below-cost sales of that model because the below-cost sales were not made in substantial quantities within an extended period of time. Where 20 percent or more of a respondent's sales of a given model were at prices less than COP, we disregarded the below-cost sales because they were made in substantial quantities within an extended period of time, in accordance with sections 773(b)(2) (B) and (C) of the Act. Based on this test, we disregarded below-cost sales for both classes or kinds of merchandise under review and for all respondents for which we conducted a cost investigation.

In accordance with section 773(a)(1)(B)(i) of the Act, where possible, we based NV on sales at the same level of trade (LOT) as the U.S. price. *See* the ''Level of Trade Section'' below.

The Department determined in the final results of a previous administrative review, *Certain Corrosion-Resistant Carbon Steel Flat Products and Certain Cut-to-Length Carbon Steel Plate From Canada: Final Results of Antidumping Duty Administrative Reviews*, 62 FR 12725 (Mar. 9, 1998), that it would be inappropriate to resort directly to constructed value (CV), in lieu of foreign market sales, as the basis for NV if the Department finds foreign market sales of merchandise identical or most similar to that sold in the United States to be below cost or otherwise outside the ''ordinary course of trade.'' Therefore, we match a given U.S. sale to foreign market sales of the next most similar model when all sales of the most comparable model fail the cost test. The Department will use CV as the basis for NV only when there are no above-cost sales that are otherwise suitable for comparison.

Therefore, in this proceeding, when making comparisons in accordance with section 771(16) of the Act, we considered all products sold in the home market as described in the ''Scope of Reviews'' section of this notice, above, that were in the ordinary course of trade for purposes of determining appropriate product comparisons to U.S. sales. Where there were no sales of identical merchandise in the home market made in the ordinary course of trade to compare to U.S. sales, we compared U.S. sales to sales of the most similar foreign like product made in the ordinary course of trade, based on the characteristics listed in Appendix V of our antidumping questionnaire.

Where appropriate, we made adjustments to NV for differences in circumstances of sale (COS), in accordance with sections 773(a)(6) and (a)(8) of the Act and 19 CFR 351.410. For comparisons to EP, we made COS

adjustments to NV by deducting home market direct selling expenses and adding U.S. direct selling expenses. We also made adjustments, where applicable, for home market indirect selling expenses to offset U.S. commissions paid on EP sales pursuant to 19 CFR 351.410(b). For comparisons to CEP, we made COS adjustments by deducting home market direct selling expenses pursuant to section 772(d) of the Act.

CCC

For those models for which there was a sufficient quantity of sales at prices above COP, we based NV on home market prices to unaffiliated parties. Home market starting prices were based on the packed, ex-factory or delivered prices to unaffiliated purchasers in the home market, net of discounts and price adjustments, where applicable.

We made adjustments, where applicable, for packing and movement expenses in accordance with sections 773(a)(6)(A) and (a)(6)(B) of the Act. We also made adjustments for differences in the costs of manufacture for subject merchandise and matching foreign like products, attributable to their differing physical characteristics, pursuant to section 773(a)(6)(C)(ii) of the Act. In accordance with 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410, for comparison to EP, we made COS adjustments to NV by deducting home market direct selling expenses (credit) and adding U.S. direct selling expenses (credit). When comparisons were made to EP sales on which commissions were paid, but where no commissions were paid on the matching foreign market sales, we made adjustments for the respondent's home market indirect selling expenses to offset these U.S. commissions pursuant to 19 CFR 351.410(e).

Dofasco

For those models for which there was a sufficient quantity of sales at prices above COP, we based NV on home market prices to unaffiliated parties. We made adjustments, where applicable, for packing and movement expenses in accordance with sections 773(a)(6)(A) and (a)(6)(B) of the Act. We also made adjustments for differences in the costs of manufacture for subject merchandise and matching foreign like products, attributable to their differing physical characteristics, pursuant to section 773(a)(6)(C)(ii) of the Act. In accordance with 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410, for comparison to EP, we made COS adjustments to NV by deducting home market direct selling expenses (credit, royalties, and warranty expenses) and adding U.S. direct selling expenses (credit, royalties, and warranty expenses). When comparisons were made to EP sales on which commissions were paid, but where no commissions were paid on the matching foreign market sales, we made adjustments for the respondent's home market indirect selling expenses to offset these U.S. commissions pursuant to 19 CFR 351.410(e).

During verification we discovered that Dofasco did not incorporate all sales order numbers in determining the cost for a few of its CONNUMs. We tested three sales order numbers and compared the costs associated with these to the reported costs for the respective product. We found that the cost calculated for two of the missing sales order numbers exceeded the reported costs for their respective products and that the cost calculated for the other sales order number was less than the cost of its respective product. For those CONNUMs whose sales order numbers we tested, we adjusted their cost in accordance with the test results. For the remaining CONNUMs, we determine that the use of facts available is appropriate, in accordance with section 776(a) of the Act, because, as discovered at verification, Dofasco failed to include all sales order numbers in its cost calculation. Where necessary information is missing from the record, the Department may apply facts available under section 776 of the Act. Further, where that information is missing because a respondent has failed to cooperate to the best of its ability, section 776(b) of the Act authorizes the Department to use facts available that are adverse to the interests of that respondent, which may include information derived from the petition, the final determination, a previous administrative review, or other information placed on the record. Dofasco did not act to the best of its ability in the reporting of its costs. Even though its sales order number documentation was readily available and company officials had knowledge of these sales order numbers, Dofasco failed to ensure that all sales order numbers were included in its cost calculations. This indicates that Dofasco did not act to the best of its ability to comply with the Department's request for information. We are therefore using an adverse inference as facts available for this aspect of Dofasco's cost calculation. For those CONNUMs whose sales order numbers we did not test, as facts available we increased their cost by adding the highest differential for the CONNUMs tested. We have also made other adjustments to Dofasco's reported costs. We increased the variable cost of manufacture by disallowing Dofasco's claimed adjustment for byproduct profits and certain sundry expenses. Finally, we have excluded capital gains and foreign exchange gains as offsets to Dofasco's interest expense. We used adjusted COP and CV values to appropriately reflect Dofasco's expenses associated with painting services provided by an affiliate. For a full discussion, *see Memorandum to the File: Analysis Memorandum for the Preliminary Results of Review for Dofasco,* August 12, 1999.

MRM

For those models for which there was a sufficient quantity of sales at prices above COP, we based NV on home market prices to unaffiliated purchasers (MRM made no home market sales to affiliated parties). Home market prices were based on the packed, ex-factory or delivered prices to purchasers in the home market.

We made adjustments to the starting price, net of rebates, for movement expenses in accordance with sections 773(a)(6)(A) and (a)(6)(B) of the Act. In accordance with section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410, for comparison to EP, we made COS adjustments to NV by deducting home market direct selling expenses (credit expense) and adding U.S. direct selling expenses (credit expense). Because comparisons were made to EP sales on which commissions were paid, but no commissions were paid on home market sales, we made adjustments for the respondent's home market indirect selling expenses to offset these U.S. commissions pursuant to 19 CFR 351.410(e).

As a result of our verification of MRM's response, we reclassified as freight expenses data originally reported as billing adjustments. Also as a result of our verification, we made an upwards adjustment to MRM's cost of manufacture before performing our sales-below-cost test. For a full discussion, *see Memorandum to the File: Analysis Memorandum for the Preliminary Results of Review for MRM,* August 12, 1999.

National

We based NV on home market prices to unaffiliated purchasers (National made no home market sales to affiliated parties). Home market prices were based on the packed, ex-factory or delivered prices to purchasers in the home market.

We made adjustments to the starting price, net of billing adjustments and discounts, for movement expenses in

accordance with sections 773(a)(6)(B)(ii) of the Act. In accordance with 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410(c), for comparison to CEP, we made COS adjustments to NV by deducting home market direct selling expenses (credit, warranty, and technical service expenses). We also made adjustments for differences in the costs of manufacturing subject merchandise and matching foreign like products, attributable to their differing physical characteristics, pursuant to section 773(a)(6)(C)(ii) of the Act. Finally, we deducted home market indirect selling expenses to the extent of U.S. indirect selling expenses because all sales in the home market were made at a different level of trade than sales in the U.S. market. See the National subsection of the ''Level of Trade'' section below.

Stelco

For those models for which there was a sufficient quantity of sales at prices above COP, we based NV on home market prices to affiliated parties (when made at prices determined to be at arms-length, in accordance with 19 CFR 351.403) or unaffiliated parties. Home market starting prices were based on the packed, ex-factory or delivered prices to affiliated or unaffiliated purchasers in the home market net of discounts and rebates. We made adjustments, where applicable, for packing and movement expenses, in accordance with sections 773(a)(6)(A) and (a)(6)(B) of the Act. We also made adjustments for differences in the costs of manufacture for subject merchandise and matching foreign like products, attributable to their differing physical characteristics, pursuant to section 773(a)(6)(C)(ii) of the Act. In accordance with 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410, for comparison to EP, we made COS adjustments to NV by deducting home market direct selling expenses (credit, advertising, warranties and technical services) and adding U.S. direct selling expenses (credit, advertising, warranties and technical services). There were no commissions paid during the POR on either home market sales or U.S. sales.

We made adjustments to COP and CV on corrosion-resistant steel to appropriately reflect Stelco's expenses associated with painting services provided by an affiliate.

Level of Trade

In accordance with section 773(a)(1)(B) of the Act, to the extent practicable, we determine NV based on sales in the comparison market at the same LOT as U.S. sales. The NV LOT is the level of the starting-price sale in the comparison market or, when NV is based on constructed value, the level of the sales from which we derive SG&A and profit. For EP, the U.S. LOT is also the level of the starting-price sale, which is usually from exporter to importer. For CEP, it is the level of the constructed sale from the exporter to the importer.

To determine whether NV sales are at a different LOT than EP or CEP, we examine stages in the marketing process and selling functions along the chain of distribution between the producer and the unaffiliated customer. If the comparison-market sales are at a different LOT, and the difference affects price comparability, as manifested in a pattern of consistent price differences between the sales on which NV is based and comparison-market sales at the LOT of the export transaction, we make an LOT adjustment under section 773(a)(7)(A) of the Act. Finally, for CEP sales, if the NV level is more remote from the factory than the CEP level and there is no basis for determining whether the difference in the levels between NV and CEP affects price comparability, we adjust NV under section 773(a)(7)(B) of the Act (the CEP offset provision). *See Notice of Final Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate from South Africa,* 62 FR 61731 (November 19, 1997).

In the present review, only Dofasco claimed that more than one LOT existed. As discussed below, to evaluate LOTs, we examined information regarding the distribution systems in both the U.S. and Canadian markets, including the selling functions, classes of customer, and selling expenses for each respondent.

CCC

In both the home market and the United States, CCC reported one LOT. CCC reported three customer categories in the home market and two in the U.S. market, but CCC claimed that the selling functions it performed were the same in each market and did not vary according to customer. CCC also reported two channels of distribution, but the Department found no difference in the functions performed through these channels of distribution. CCC did not claim a LOT adjustment.

We analyzed the selling functions performed for various customer categories and channels of distribution in each market. We found that CCC performed substantially similar selling functions regardless of the type of home market customer and, therefore, that one level of trade existed in the home market. We reached the same conclusion regarding the U.S. market.

Finally, we compared the selling functions performed at the home market LOT with those performed at the U.S. LOT and found them substantially similar. Thus, no LOT adjustment was appropriate. For a further discussion of the Department's LOT analysis with respect to CCC, *see Memorandum to the File: Analysis Memorandum for the Preliminary Results of Review for CCC,* August 12, 1999.

Dofasco

Dofasco reported three LOTs in the home market. Dofasco defined its LOT categories by customer category: service center, automotive, and construction and converters/manufacturers (''construction''). We examined the selling functions performed at each claimed level and found that there was a significant difference in selling functions offered to these three categories. Of the several reported selling functions, Dofasco performed only two of the same or similar selling functions at both the automotive and service center sales levels. Dofasco reported fourteen selling functions which were different between these two levels. Additionally, sales to automotive customers are sales to end users, while sales to service centers are sales to resellers. Thus, sales to service centers and automotive customers were made at different stages of marketing. Based upon this fact and the different levels of selling functions described above, we preliminarily conclude that sales to the automotive customers and service centers are made at different levels of trade.

Although both automotive and construction customers are OEMs, we note that both quantitatively and qualitatively, the selling functions offered to automotive customers involve significantly greater selling activities and thus represent a distinct stage of marketing. Specifically, of the 16 reported selling functions, Dofasco performed only seven of the same or similar selling functions to both automotive and construction customers. Dofasco's functions for these two customer categories differed with respect to nine other activities. Therefore, given these differences, we preliminarily conclude that automotive and construction constitute separate levels of trade.

There were numerous differences in selling functions between sales to construction and service center customers. Dofasco performed six reported selling functions for sales to service centers and only four selling

functions for sales to construction customers. Of these selling functions, only one was performed for both service centers and construction customers. Additionally, sales to service center customers are sales to resellers, while sales to construction customers are sales to end users. Thus, sales to service centers and construction customers were made at different stages of marketing. Based upon this fact and the different levels of selling functions described above, we preliminarily conclude that sales to service centers and construction customers are made at different levels of trade.

Overall, we determine that the selling functions for the automotive, service center, and construction customer categories are substantially dissimilar to one another and that these sales are made at different stages of marketing. Therefore, we preliminarily determine that the automotive, service center, and construction customer categories should be treated as three LOTs in the comparison market. Dofasco reported the same three LOTs in the U.S. market: automotive, service center, and construction. We preliminarily determine that the results of our analysis of U.S. LOTs are identical to those of the comparison market. In addition, there were only insignificant differences in selling functions at each LOT between the comparison market and the U.S. market. Therefore, we found that the three U.S. LOTs corresponded to the three comparison market LOTs. The Department did not find that there existed a pattern of consistent price differences between the three levels of trade. Therefore, we did not make LOT adjustments when comparing sales at different LOTs. For a further discussion of the Department's LOT analysis with respect to Dofasco, see *Memorandum to the File: Analysis Memorandum for the Preliminary Results of Review for Dofasco,* August 12, 1999.

MRM

In both the home market and the United States, MRM reported one LOT and one distribution system with two classes of customers in the home market, distributors and OEMs, and one class of customer, OEMs, in the U.S. market. We analyzed the selling functions and activities performed for customers in each market. We found that MRM performed substantially similar selling functions and activities for both classes of home market customers and, therefore, that one level of trade existed in the home market. Finally, we compared the selling functions performed at the home market LOT with those performed at the U.S. LOT and found them substantially similar. Thus, no LOT adjustment was appropriate.

National

National claimed only one LOT, but reported several different distribution channels in both its home market and the United States based on classes of customers (OEMs and steel service centers) and the existence of warehousing or further manufacturing between National and its customers.

We examined the reported selling functions and found that National provides substantially the same selling functions to its home market customers regardless of distribution channel. We reached the same conclusion regarding the U.S. market.

National does not provide technical services to its service center customers. We did not, however, consider the provision of technical services to constitute a substantial difference between distribution channels. National warehouses some of its products before shipping to customers. Any one sale, however, can contain both warehoused and non-warehoused products and the Department was unable to determine which sales involved more warehoused goods than others.

We compared the channels of distribution and selling functions in the U.S. and home markets. The channels of distribution are similar for both markets with National providing substantially similar selling functions to both its U.S. and home market customers. However, at the level of constructed export sale to the United States, i.e., after eliminating from consideration the selling functions associated with deductions made under section 772 of the Act, we found that National's sales to customers in the United States were made at a different level of trade than its sales to home market customers.

Because there are no sales in the home market made at the same level of trade as sales in the United States, we were not able to determine whether the difference in level of trade affects price comparability. Therefore, we made a constructed export price offset. In accordance with 19 CFR 351.408(f)(2), we deducted indirect selling expenses from NV to the extent of U.S. indirect selling expenses. For a further discussion of the Department's LOT analysis with respect to National, see *Memorandum to the File: Analysis Memorandum for the Preliminary Results of Review for National,* August 12, 1999.

Stelco

Stelco identified one level of trade and two channels of distribution (to end-users or to resellers) in the home market for each class or kind of merchandise. We examined the selling functions performed in each channel and found that Stelco provided many of the same or similar selling functions in each, including inventory maintenance, warranty, technical advice, and freight and delivery arrangements. We found few differences between selling functions for transactions made through the two channels of trade. Overall, we determine that the selling functions between the two sales channels are sufficiently similar to consider them one LOT in the home market for sales of both corrosion-resistant products and plate products.

In the United States, Stelco Inc. sold both products through the two channels of distribution listed above. We found that the selling functions performed for sales to the United States are sufficiently similar between the two channels to consider them one LOT for both corrosion-resistant products and plate products. Additionally, we consider this LOT to be the same as that identified in the home market. Therefore, no adjustment is appropriate.

Preliminary Results of Reviews

As a result of our reviews, we preliminarily determine the weighted-average dumping margins for the period August 1, 1997 through July 31, 1998 to be as follows:

Manufacturer/Exporter	Margin percentage
Certain Corrosion-Resistant Carbon Steel Flat Products	
CCC	1.08
Dofasco	0.11
National	5.65
Stelco	4.24
Certain Cut-to-Length Carbon Steel Plate	
MRM	0.00
Stelco	0.00

The Department will disclose to the parties to the proceeding calculations performed in connection with these preliminary results of review within ten days after the date of public announcement, or, if there is no public announcement, within five days after the date of publication of these preliminary results of review.

Any interested party may request a hearing within 30 days of publication. Any hearing, if requested, will be held 37 days after the date of publication or

the first business day thereafter. Case briefs from interested parties may be submitted not later than 30 days after publication. Rebuttal briefs, limited to issues raised in case briefs, may be filed not later than five days after the date of filing of case briefs. The Department will publish the final results of this administrative review, including its analysis of issues raised in the case and rebuttal briefs, not later than 120 days after the date of publication of this notice.

Upon issuance of the final results of review, the Department shall determine, and the U.S. Customs Service shall assess, antidumping duties on all appropriate entries. In accordance with 19 CFR 351.212(b), we calculated importer-specific ad valorem duty assessment rates for each class or kind of merchandise based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total customs value of the sales used to calculate those duties. This rate will be assessed uniformly on all entries of that particular importer for that class or kind of merchandise made during the POR.

If the revocation is made final for MRM, it will apply to all unliquidated entries of this merchandise produced by MRM, exported to the United States and entered, or withdrawn from warehouse, for consumption, on or after August 1, 1998, which will be the effective date of the revocation from the order for MRM.

Furthermore, the following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a) of the Act: (1) the cash deposit rate for each reviewed company will be that established in the final results of review (except that no deposit will be required for firms with *de minimis* margins, i.e., margins less than 0.5 percent); (2) for exporters not covered in this review, but covered in the less than fair value (LTFV) investigation or a previous review, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a previous review, or the LTFV investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; (4) the cash deposit rate for all other manufacturers or exporters will continue to be the ''all others'' rate established in the LTFV investigation, which was 18.71 percent for corrosion-resistant steel products and 61.88 percent for plate (*see Amended Final Determinations of Sales at Less Than Fair Value and Antidumping Orders: Certain Corrosion-Resistant Carbon Steel Flat Products and Certain Cut-to-Length Carbon Steel Plate From Canada,* 60 FR 49582 (Sep. 26, 1995)). These requirements, when imposed, shall remain in effect until publication of the final results of the next administrative reviews.

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

These administrative reviews and notices are published in accordance with sections 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 777(i)(1) of the Act (19 U.S.C. 1677f(i)(1)).

Dated: August 10, 1999.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

[FR Doc. 99–21568 Filed 8–18–99; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–821–811]

Initiation of Antidumping Duty Investigation: Solid Fertilizer Grade Ammonium Nitrate From the Russian Federation

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: August 19, 1999.

FOR FURTHER INFORMATION CONTACT: Rick Johnson at (202) 482–3818, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230.

INITIATION OF INVESTIGATION:

The Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (''the Act'') by the Uruguay Round Agreements Act (''URAA''). In addition, unless otherwise indicated, all citations to the Department's regulations are references to the provisions codified at 19 CFR Part 351 (1998).

The Petition

On July 23, 1999, the Department of Commerce (''the Department'') received a petition filed in proper form by the Committee for Fair Ammonium Nitrate Trade (''COFANT'' or ''petitioner''), whose members are domestic producers of solid fertilizer grade ammonium nitrate. The Department received supplemental information to the petition on August 6, 1999.

In accordance with section 732(b) of the Act, petitioner alleges that imports of fertilizer grade ammonium nitrate from the Russian Federation (''Russia'') are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Act, and that such imports are materially injuring an industry in the United States.

The Department finds that petitioner filed the petition on behalf of the domestic industry because it is an interested party as defined in sections 771(9)(C) and (F) of the Act and has demonstrated sufficient industry support with respect to the investigation it is requesting the Department to initiate (*see Determination of Industry Support for the Petition below*).

Scope of Investigation

For purposes of this investigation, the products covered are solid, fertilizer grade ammonium nitrate products, whether prilled, granular or in other solid form, with or without additives or coating, and with a bulk density equal to or greater than 53 pounds per cubic foot. Specifically excluded from this scope is solid ammonium nitrate with a bulk density less than 53 pounds per cubic foot (commonly referred to as industrial or explosive grade ammonium nitrate).

The merchandise subject to this investigation is classified in the Harmonized Tariff Schedule of the United States (''HTSUS'') at subheading 3102.30.00.00. Although the HTSUS subheadings are provided for convenience and Customs purposes, the written description of the merchandise under investigation is dispositive.

During our review of the petition, we discussed the scope with petitioner to ensure that the scope in the petition accurately reflects the product for which the domestic industry is seeking relief. Moreover, as we discussed in the preamble to the Department's regulations (62 FR 27323), we are setting aside a period for parties to raise issues regarding product coverage. In particular, we seek comments on the

specific densities of fertilizer grade ammonium nitrate set out in the description above. The Department encourages all parties to submit such comments by August 23, 1999. Comments should be addressed to Import Administration's Central Records Unit at Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, D.C. 20230. The period of scope consultations is intended to provide the Department with ample opportunity to consider all comments and consult with parties prior to the issuance of the preliminary determination.

Determination of Industry Support for the Petitions

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (1) at least 25 percent of the total production of the domestic like product; and (2) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition.

Section 771(4)(A) of the Act defines the ''industry'' as the producers of a domestic like product. Thus, to determine whether the petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (''ITC''), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product (section 771(10) of the Act), they do so for different purposes and pursuant to separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to the law.[1]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation,'' *i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition. Moreover, petitioner does not offer a definition of domestic like product distinct from the scope of the investigation.

The domestic like product referred to in the petition is the single domestic like product defined in the ''Scope of the Investigation'' section, above. The Department has no basis on the record to find the petitioner's definition of domestic like product to be inaccurate. We found that petitioner submitted sufficient reasonably available information that there is a clear dividing line between fertilizer and explosive grade ammonium nitrate based on their physical characteristics and uses. The Department has, therefore, adopted the domestic like product definition set forth in the petition.

The Department has determined that the petition contains accurate and adequate evidence of industry support because petitioner established industry support representing 74 percent of total production of the domestic like product (*see Attachment to the Initiation Checklist, Re: Industry Support,* August 12, 1999).

Accordingly, the Department determines that this petition is filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.

Export Price and Normal Value

Petitioner identified (1) JSC Angarsk Petrochemical Co., (2) JSC Berezniki Azot, (3) JCS Cherepovets PO Azot, (4) JSC Dorogobuzh, (5) JSC Kemerovo ''Azot,'' (6) JSC Kirovo-Chepetsk, (7) JSC Meleuz Prod. Assoc. Minudobreniya, (8) JSC Nevinnomysskiy Azot, (9) JSC Acron, (10) JSC Novomendeleyevsk Chemical Plant, (11) JSC Novomoskovsk AK ''Azot,'' (12) JSC ''Minudobreniya'', and (13) JSC ''Kuybyshevazot'' as possible producers/exporters of solid fertilizer grade ammonium nitrate from Russia. Petitioner further asserted that two of these producers, JSC Acron and JSC Nevinnomysskiy Azot, have exported significant amounts of ammonium nitrate into the United States during the last twelve months.

Petitioner based export price (''EP'') on two methods: (1) import values declared to the U.S. Customs Service during the anticipated period of investigation (''POI''); and (2) an actual U.S. selling price known to petitioner based on a quote in the anticipated POI provided by a U.S. importer on an ex-factory basis. Petitioner based its calculation of EP on the average unit value (customs value) of ammonium nitrate from Russia, as provided by the U.S. Bureau of the Census, for the applicable HTSUS category (3102.30) for the period January, 1999 through May, 1999. Petitioner deducted foreign inland freight from the customs value in order to obtain ex-factory prices. In order to calculate foreign inland freight, petitioner used Polish rail and truck rates because the per-capita GNP of Poland is much closer to Russia's GNP than is U.S. GNP, and because petitioner found transport rates on a per ton basis, based on distance traveled. Petitioner also used the Polish transport rates because they were the only published reasonably available to petitioner, and petitioner had no reasonable basis to know whether Russian producers relied on truck or rail transport to move the product from plant to port. Petitioner calculated foreign inland freight for the two significant producers noted above. Using estimated distances for each of these producers, petitioner calculated both a rail freight and truck freight estimate, and calculated normal values (''NV'') based on each of these estimates. Based on the information provided by petitioner, we believe that the use of Polish transport rates represents accurate and adequate information reasonably available to petitioner and is acceptable for purposes of initiation of this investigation.

In order to calculate actual U.S. selling prices known to petitioner, petitioner relied on a quote offered to an unaffiliated purchaser. Because the price was based on a ex-factory basis, no adjustments were made for foreign inland freight.

Petitioner asserted that Russia is a non-market economy country (''NME'') to the extent that sales or offers for sale of such or similar merchandise in Russia or to third countries do not permit calculation of NV under 19 CFR 351.404. Petitioner, therefore, constructed NV based on the factors of production methodology pursuant to section 773(c) of the Act. In previous investigations, the Department has determined that Russia is an NME. *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Hot-Rolled Flat-Rolled Carbon-Quality Steel Products from the Russian Federation,* 64 FR 38626 (July 19, 1999) (''*Russian HR Steel*''). In accordance with section

[1] *See Algoma Steel Corp. Ltd.,* v. *United States,* 688 F. Supp. 639, 642–44 (CIT 1988); *High Information Content Flat Panel Displays and Display Glass Therefore from Japan: Final Determination; Rescission of Investigation and Partial Dismissal of Petition,* 56 FR 32376, 32380–81 (July 16, 1991).

771(18)(C)(i) of the Act, a determination of NME status remains in effect until revoked by the Department. The determination of NME status for Russia has not been revoked by the Department and, therefore, remains in effect for purposes of the initiation of this investigation. Accordingly, the NV of the product appropriately is based on factors of production valued in a surrogate market economy country in accordance with section 773(c) of the Act. In the course of this investigation, all parties will have the opportunity to provide relevant information related to the issues of Russia's NME status and the granting of separate rates to individual exporters. *See, e.g., Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the PRC,* 59 FR 22585 (May 2, 1994).

For the calculation of NV, petitioner based the factors of production, as defined by section 773(c)(3) of the Act (raw materials, labor, energy and capital cost), for ammonium nitrate on the quantities of inputs used by a representative U.S. producer. Petitioner stated that it was unable to furnish information on Russian factors of production. Thus, petitioner has assumed, for purposes of the petition, that producers in Russia use the same inputs in the same quantities as petitioner. Because data regarding the quantities of inputs used by Russian producers was not reasonably available to petitioner, for purposes of this initiation we have accepted petitioner's U.S. quantities.

Petitioner selected Poland as its primary surrogate. Petitioner stated that the per-capita GNP of Poland differs only slightly from that of Russia and, thus, it maintains that Poland is the most suitable surrogate among the potential surrogates, because it is at a comparable level of economic development and is a significant producer of comparable merchandise (in accordance with section 773(c)(4) of the Act). Based on the information provided by petitioner, we believe that the petition contains adequate and accurate information supporting its allegation for using Poland as a surrogate country for purposes of initiation of this investigation.

In accordance with section 773(c)(4) of the Act, petitioner valued factors of production, where possible, on reasonably available, public surrogate country data. Labor was valued using the regression-based wage rate for Russia provided by the Department, in accordance with 19 CFR 351.408(c)(3). Electricity and natural gas were valued using the rate for Poland published in a quarterly report of the OECD's International Energy Agency for the fourth quarter of 1998. Petitioner attempted to obtain Polish import values for materials used in the production of ammonium nitrate, but stated that it could not reasonably obtain publicly available surrogate information from a comparable economy. Because petitioner could not reasonably identify this information for materials used in the production of ammonium nitrate (chemicals, stabilizers, coating agents and catalysts), petitioner relied on costs incurred by the U.S. producer to value the usage requirements, which represent only a small portion of total production costs. For overhead (exclusive of depreciation), depreciation, general expenses, and profit, petitioner applied rates derived from the 1997 public annual report of a Polish producer of subject merchandise, Zaklady Azotowe Kedzierzyn (''ZAK''). For purposes of initiation, we made two minor revisions to general expenses. For a further discussion of this revision, *see Initiation Checklist,* page 6, and Attachment III, dated August 12, 1999. Based on the information provided by petitioner, we believe that the surrogate values represent information reasonably available to petitioner and are acceptable for purposes of initiation of this investigation. For a more detailed discussion of home market price, U.S. price, factors of production and sources of data, *see Initiation Checklist,* dated August 12, 1999. Should the need arise to use as facts available under section 776 of the Act any of this information in our preliminary or final determinations, we may re-examine the information and revise the margin calculations, if appropriate.

Based on comparisons of EP to NV, calculated in accordance with section 773(c) of the Act, the calculated dumping margins for ammonium nitrate from Russia range from 112.08 to 357.09 percent.

Fair Value Comparisons

Based on the data provided by petitioner, there is reason to believe that imports of solid fertilizer grade ammonium nitrate from Russia are being, or are likely to be, sold at less than fair value.

Critical Circumstances

Petitioner has alleged that critical circumstances exist with regard to imports of solid fertilizer grade ammonium nitrate from Russia, and has supported its allegations with the following information.

First, petitioner claims that there is a history of injurious dumping of the subject merchandise by Russian producers. Petitioner argues that the Department considers the existence of an antidumping duty order covering the subject merchandise in another country as sufficient evidence of a history of injurious dumping. Petitioner provided a copy of a 1995 antidumping order imposed by the European Union on imports of Russian ammonium nitrate (*see* Exhibit 32, Petition dated July 23, 1999). Since this order is still in effect, petitioner claims that there is a history of injurious dumping by Russian producers of the subject merchandise.

Petitioner also has alleged that imports from Russia have been massive over a relatively short period. Alleging that there was sufficient pre-filing notice of the antidumping duty petition, petitioner contends that the Department should compare imports during September–December 1998 (base period) to imports during January–April 1999 (comparison period) for purposes of this determination, as provided in 19 CFR. 351.206(h)(2)(i). Specifically, petitioner supported this allegation with copies of news articles discussing the likelihood of filing antidumping complaints against Russian ammonium nitrate producers. *See* Petition dated July 23, 1999, Exhibit 37. According to the import statistics contained in the petition, during the time periods petitioner has requested for comparison, imports of ammonium nitrate from Russia increased by 270.35 percent (based on volume) from the period September–December 1998 to the period January–April 1999.

In the instant case, the increase in imports was more than fifteen times the amount considered ''massive.'' Taking into consideration the foregoing, we find that petitioner has alleged the elements of critical circumstances and supported them with information reasonably available for purposes of initiating a critical circumstances inquiry. For these reasons, we will investigate this matter further and will make a preliminary determination at the appropriate time, in accordance with section 735(e)(1) of the Act and Department practice (*see* Policy Bulletin 98/4 (63 FR 55364, October 15, 1998)).

Allegations and Evidence of Material Injury and Causation

Petitioner alleges that the U.S. industry producing the domestic like product is being materially injured, and is threatened with material injury, by reason of the individual and cumulated imports of the subject merchandise sold at less than NV. Petitioner explained that the industry's injured condition is evident in the declining trends in net

operating profits, net sales volumes, as well as domestic prices of ammonium nitrate. The allegations of injury and causation are supported by relevant evidence including U.S. Customs import data, lost sales, and pricing information. The Department assessed the allegations and supporting evidence regarding material injury and causation and determined that these allegations are supported by accurate and adequate evidence and meet the statutory requirements for initiation (*see Attachments to Initiation Checklist, Re: Material Injury,* August 12, 1999).

Initiation of Antidumping Investigation

Based upon our examination of the petition on solid fertilizer grade ammonium nitrate and petitioner's responses to our supplemental questionnaire clarifying the petition, we have found that the petition meets the requirements of section 732 of the Act. Therefore, we are initiating an antidumping duty investigation to determine whether imports of solid fertilizer grade ammonium nitrate from Russia are being, or are likely to be, sold in the United States at less than fair value. Unless this deadline is extended, we will make our preliminary determinations no later than 140 days after the date of this initiation.

Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Act, a copy of the public version of the petition has been provided to the representatives of Russia. We will attempt to provide a copy of the public version of the petition to each exporter named in the petition, as appropriate.

International Trade Commission Notification

We have notified the ITC of our initiations, as required by section 732(d) of the Act.

Preliminary Determination by the ITC

The ITC will determine, by no later than September 7, 1999, whether there is a reasonable indication that imports of solid fertilizer grade ammonium nitrate from Russia are causing material injury, or threatening to cause material injury, to a U.S. industry. A negative ITC determination will result in the investigation being terminated; otherwise, this investigation will proceed according to statutory and regulatory time limits.

This notice is published pursuant to section 777(i) of the Act.

Dated: August 12, 1999.

Bernard Carreau,

Acting Assistant Secretary for Import Administration.

[FR Doc. 99–21569 Filed 8–18–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Overseas Trade Missions: 1999 Trade Missions (October and December); Private Sector Participants Recruitment and Selection

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce invites U.S. companies to participate in the following overseas trade missions to be held between October and December 1999. For a more complete description of the trade mission, obtain a copy of the mission statement from the Project Officer indicated below. The recruitment and selection of private sector participants for these missions will be conducted according to the Statement of Policy Governing Department of Commerce Overseas Trade Missions announced by Secretary Daley on March 3, 1997.

Textile Trade Mission to Mexico, Mexico City and Guadalajara, Mexico, October 24–28, 1999. Recruitment closes September 10, 1999.

FOR FURTHER INFORMATION CONTACT: Bill Dawson, U.S. Department of Commerce, Tel: 202–482–5155 or Rachael Alarid, U.S. Department of Commerce, Tel: 202–482–5154, Fax: 202–482–2859.

Textile Home Furnishing Products Trade Mission, China, Taiwan, and the Philippines, November 29–December 7, 1999. Recruitment closes October 15, 1999.

FOR FURTHER INFORMATION CONTACT: Lawrence Brill, U.S. Department of Commerce, Tel: 202–482–1856, Fax: 202–482–2859; Reginald Beckham, U.S. Department of Commerce, Tel: 202–482–5478, Fax: 202–482–1999.

Dated: August 13, 1999.

Tom Nisbet,

Director, Promotion Planning and Support Division, Office of Export Promotion Coordination.

[FR Doc. 99–21533 Filed 8–18–99; 8:45 am]

BILLING CODE 3510–DR–P

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton, Wool and Man-Made Fiber Textiles and Textile Products and Silk Blend and Other Vegetable Fiber Apparel Produced or Manufactured in the Philippines

August 12, 1999.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: August 19, 1999.

FOR FURTHER INFORMATION CONTACT: Janet Heinzen, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482094212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port, call (202) 927095850, or refer to the U.S. Customs website at http://www.customs.ustreas.gov. For information on embargoes and quota re-openings, call (202) 482093715.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being adjusted for special shift.

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 63 FR 71096, published on December 23, 1998). Also see 63 FR 67050, published on December 4, 1998.

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

August 12, 1999.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 30, 1998, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool and man09made fiber textiles and textile products and silk blend and other vegetable fiber apparel, produced or manufactured in

the Philippines and exported during the twelve-month period which began on January 1, 1999 and extends through December 31, 1999.

Effective on August 19, 1999, you are directed to adjust the limits for the following categories, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit1A[1]
Levels in Group I	
352/652	2,212,828 dozen.
36909S1A[2]	9,917 kilograms.
611	5,201,529 square meters.
633	56,384 dozen.
636	1,910,481 dozen.
643	606,355 numbers.
645/646	736,831 dozen.
649	5,714,665 dozen.
65909H1A[3]	1,659,613 kilograms.
847	330,211 dozen.
Group II	
20009227, 30009326, 332, 35909O1A[4], 360, 362, 363, 36909O1A[5], 40009414, 43409438, 440, 442, 444, 448, 459pt.1A[6], 464, 469pt.1A[7], 60009607, 61309629, 644, 65909O1A[8], 666, 66909O1A[9], 67009O1A[10], 831, 83309838, 84009846, 85009858 and 859pt.1A[11], as a group.	239,200,611 square meters equivalent.

[1]1AThe limits have not been adjusted to account for any imports exported after December 31, 1998.

[2]1ACategory 36909S: only HTS number 6307.10.2005.

[3]1ACategory 65909H: only HTS numbers 6502.00.9030, 6504.00.9015, 6504.00.9060, 6505.90.5090, 6505.90.6090, 6505.90.7090 and 6505.90.8090.

[4]1ACategory 35909O: all HTS numbers except 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, 6211.42.0010 (Category 35909C); and 6406.99.1550 (Category 359pt.).

[5]1ACategory 36909O: all HTS numbers except 6307.10.2005 (Category 36909S); 5601.10.1000, 5601.21.0090, 5701.90.1020, 5701.90.2020, 5702.10.9020, 5702.39.2010, 5702.49.1020, 5702.49.1080, 5702.59.1000, 5702.99.1010, 5702.99.1090, 5705.00.2020 and 6406.10.7700 (Category 369pt.).

[6]1ACategory 459pt.: all HTS numbers except 6405.20.6030, 6405.20.6060, 6405.20.6090, 6406.99.1505 and 6406.99.1560.

[7]1ACategory 469pt.: all HTS numbers except 5601.29.0020, 5603.94.1010 and 6406.10.9020.

[8]1ACategory 65909O: all HTS numbers except 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, 6211.43.0010 (Category 65909C); 6502.00.9030, 6504.00.9015, 6504.00.9060, 6505.90.5090, 6505.90.6090, 6505.90.7090, 6505.90.8090 (Category 65909H); 6406.99.1510 and 6406.99.1540 (Category 659pt.).

[9]1ACategory 66909O: all HTS numbers except 6305.32.0010, 6305.32.0020, 6305.33.0010, 6305.33.0020, 6305.39.0000 (Category 66909P); 5601.10.2000, 5601.22.0090, 5607.49.3000, 5607.50.4000 and 6406.10.9040 (Category 669pt.).

[10]1ACategory 67009O: all HTS numbers except 4202.12.8030, 4202.12.8070, 4202.92.3020, 4202.92.3031, 4202.92.9026 and 6307.90.9907 (Category 67009L).

[11]1ACategory 859pt.: only HTS numbers 6115.19.8040, 6117.10.6020, 6212.10.5030, 6212.10.9040, 6212.20.0030, 6212.30.0030, 6212.90.0090, 6214.10.2000 and 6214.90.0090.

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. 99–21478 Filed 8–18–99; 8:45 am]

BILLING CODE 3510–DR–F

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 99–C0007]

Consolidated Electrical Distributors, Inc., a Domestic Corporation, Provisional Acceptance of a Settlement Agreement and Order; Correction

AGENCY: Consumer Product Safety Commission.

ACTION: Notice; Correction.

SUMMARY: The Consumer Product Safety Commission published a document in the **Federal Register** of August 12, 1999, pages 43990 through 43992, concerning the provisional acceptance of a settlement agreement and order with Consolidated Electrical Distributors, Inc. The Summary section of the document contained an erroneous reference to a civil penalty. Payments under this Agreement are not a civil penalty. See Paragraph 33 of the Agreement.

FOR FURTHER INFORMATION CONTACT: Howard N. Tarnoff, Trial Attorney, Office of Compliance, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0626, x1382.

Correction

In the **Federal Register** issue of August 12, 1999, 64 FR 43990, in the second sentence in the Summary, remove the words, ''containing a civil penalty of $1,500,000.''

Dated: August 13, 1999.

Sadye E. Dunn,

Secretary.

[FR Doc. 99–21474 Filed 8–18–99; 8:45 am]

BILLING CODE 6355–01–M

DEPARTMENT OF DEFENSE

Defense Finance and Accounting Service

Privacy Act of 1974; System of Records

AGENCY: Defense Finance and Accounting Service, DoD.

ACTION: Notice to amend systems of records.

SUMMARY: The Defense Finance and Accounting Service proposes to amend systems of records notices in its inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended. The amendment consists of correcting a Federal statute cite from '14 U.S.C. 1681a(f)' to '15 U.S.C. 1681a(f)' within all of the Defense Finance and Accounting Service systems of records notices.

DATES: This action will be effective August 19, 1999.

ADDRESSES: Defense Finance and Accounting Service, 1931 Jefferson Davis Highway, ATTN: DFAS/CEE, Arlington, VA 22240-5291.

FOR FURTHER INFORMATION CONTACT: Mrs. Pauline Korpanty at (703) 607-3832.

SUPPLEMENTARY INFORMATION: The complete inventory of Defense Finance and Accounting Service record system notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and is available from the address above.

The amendment consists of correcting a Federal statute cite from '14 U.S.C. 1681a(f)' to '15 U.S.C. 1681a(f)' within all of the Defense Finance and Accounting Service systems of records notices.

Dated: August 11, 1999.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 99–21236 Filed 8–18–99; 8:45 am]

BILLING CODE 5001–10–F

DEPARTMENT OF DEFENSE

Department of the Army

Armed Forces Epidemiological Board (AFEB); Meeting

AGENCY: Office of The Surgeon General, DOD.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a)(2) of Public Law 92–463, The Federal Advisory Committee Act, this announces the forthcoming AFEB subcommittee meeting. This Board will meet from 0730–1600 on Tuesday, September 14, and Wednesday, September 15, 1999. The purpose of the meeting is to address pending and new Board issues, provide briefings for Board members on topics related to ongoing and new Board issues, conduct subcommittee meetings, and conduct an executive working session.

The meeting location will be at the Uniformed Services University of Health Sciences (USUHS), Bethesda, Maryland.

2. This meeting will be open to the public but limited by space accommodations. Any interested person may attend, appear before or file statements with the committee at the time and in the manner permitted by the committee.

FOR FURTHER INFORMATION CONTACT: COL Benedict Diniega, AFEB Executive Secretary, Armed Forces Epidemiological Board, Skyline Six, 5109 Leesburg Pike, Room 682, Falls Church, Virginia 22041–3258, (703) 681–8012/4.

SUPPLEMENTARY INFORMATION: None.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 99–21541 Filed 8–18–99; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Performance Review Boards Membership

AGENCY: Department of the Army, DoD.

ACTION: Notice.

SUMMARY: Notice is given of the names of members of the Performance Review Boards for the Department of the Army.

EFFECTIVE DATE: August 12, 1999.

FOR FURTHER INFORMATION CONTACT: Marilyn D. Ervin, U.S. Army Senior Executive Service Office, Assistant Secretary of the Army (Manpower and Reserve Affairs), 111 Army Pentagon, Washington, DC 20310–0111.

SUPPLEMENTARY INFORMATION: Section 4314(c)(1) through (5) of Title 5, U.S.C., requires each agency to establish, in accordance with regulations, one or more Senior Executive Service performance review boards. The boards shall review and evaluate the initial appraisal of senior executives' performance by supervisors and make recommendations to the appointing authority or rating official relative to the performance of these executives.

The members of the Performance Review Board for the Chief of Staff are:

1. Mr. John W. Matthews, Director, U.S. Army Records Management and Declassification Agency, Office of the Deputy Chief of Staff for Personnel (DCSPER).
2. Dr. Robin Buckelew, Director, Center for Land Warfare, Office of the Assistant Vice Chief of Staff.
3. BG Robert Glacel, Commander, U.S. Army Test and Experimentation Command, U.S. Army Operational Test Evaluation Command (OPTEC).
4. MG Albert Madora, Commander, (OPTEC).
5. Mr. Robert N. Kittel, Special Assistant for Communications & Transportation, U.S. Army Legal Services Agency.
6. BG Michael Marchand, Commander, U.S. Army Legal Services Agency.
7. BG Joseph R. Barnes, Assistant Judge Advocate General for Military Law and Operations.
8. BG Bruce M. Lawlor, Deputy Director, Operations, Readiness and Mobilization, Office of the Deputy Chief of Staff for Operations and Plans (DCSOPS).
9. BG John S. Brown, Chief of Military History, U.S. Army Center of Military History.
10. Dr. Jeffrey J. Clarke, Chief Historian, U.S. Army Center of Military History.
11. MG Mario F. Montero, Jr., Assistant Deputy Chief of Staff for Logistics.
12. Ms. Donna Shands, Acting Director for Maintenance, Office of the Deputy Chief of Staff for Logistics (DCSLOG).
13. Mr. William Neal, Acting Director for Transportation and Troop Support (DCSLOG).
14. Ms. Janet C. Menig, Deputy Assistant Chief of Staff for Installation Management, Office of the Assistant Chief of Staff for Installation Management (ACSIM).
15. Mr. Edgar B. Vandiver, Director, Center for Army Analysis (CAA).
16. Mr. Daniel J. Shedlowski, Technical Director, CAA.
17. Ms. Maureen Lishcke, Program Manager, Reserve Component Automation System, National Guard Bureau (NGB).
18. Mr. Warren Freeman, Director, D.C. National Guard.

The members of the Performance Review Board for the Army Acquisition Executive are:

Army Acquisition Executive Potential Board Members

1. Mr. A.Q. Oldacre, Deputy Program Executive Officer (PEO), Air & Missile Defense.
2. Mr. Edward Bair, Deputy PEO, Intelligence & Electronic Warfare.
3. Mr. Paul Bogosian, Deputy PEO, Aviation.
4. LTG William Campbell, Director of Information Systems for Command, Control, Communications and Computers, Office of the Secretary of the Army.
5. MG John Mechitsch, PEO, GCSS.
6. Dr. Shelba Proffitt, Program Manager, National Missile Defense.
7. Mr. Stanley H. Levine, Deputy Director, Army Digitization Office.
8. Mr. Robert R. Lehnes, Deputy PEO, Communication Systems.
9. Ms. Vicky Armbruster, Deputy PEO, Tactical Missiles.
10. Mr. Albert P. Puzzuoli, Deputy PEO, Armored Systems Modernization.
11. Mr. James Bacon, Program Manager for Chemical Demilitarization Operations.
12. Mr. T. Kevin Carroll, PEO, Standard Army Management Information Systems.
13. Dr. James Edgar, Director, Procurement Policy & Acquisition Reform, Office of the Assistant Secretary of the Army (Acquisition, Logistics & Technology).

The members of the Performance Review Board for the U.S. Army Consolidated Commands are:

1. Mr. William S. Rich, Director, National Ground Intelligence Center, U.S. Army Intelligence and Security Command (INSCOM).
2. Mr. David E. Wright, Director, Infrastructure, Logistics & Civil Emergency Planning Division (NATO).
3. Mr. Mark J. Lumer, Principal Assistant Responsible for Contracting, U.S. Army Space and Missile Defense Command (SMDC).
4. Mr. Laurence H. Burger, Director, Space and Missile Defense Battle Lab (SMDC).
5. Dr. Darrell Collier, Chief Scientist, (SMDC).
6. Mr. Joseph H. Plunkett, Assistant Deputy Chief of Staff for Personnel & Installation Management, U.S. Army Forces Command (FORSCOM).
7. Mr. Stephen J. Koons, Assistant Deputy Chief of Staff for Logistics and Readiness (FORSCOM).

8. MG Geoffrey D. Miller, Deputy Chief of Staff for Personnel & Installation Management (FORSCOM).
9. Mr. William R. Lucas, Deputy to the Commander, U.S. Army Military Traffic Management Command (MTMC).
10. BG Daniel Doherty, Assistant Deputy Chief of Staff for Base Operations Support, U.S. Army Training and Doctrine Command (TRADOC).
11. Mr. Robert J. Jefferis, Assistant Deputy Chief of Staff for Resource Management (TRADOC).
12. Mr. Philip Sakowitz, Jr., Deputy Chief of Staff for Base Operations Support (TRADOC).
13. Mr. John Kohler, Assistant Deputy Chief of Staff for Resource Management, U.S. Army, Europe (USAREUR).
14. Mr. Walter W. Hollis, Deputy Under Secretary of the Army (Operations Research).

The members of the Performance Review Board for the U.S. Army Materiel Command are:

1. MG Larry G. Smith, Commander, U.S. Army Security Assistance Command, U.S. Army Materiel Command.
2. MG David Gust, PEO-Intelligence and Electronic Warfare.
3. BG John Geis, Commanding General, U.S. Army Armaments Research, Development and Engineering Center, U.S. Army Materiel Command.
4. Mr. Gary A. Tull, Principal Deputy for Acquisition, U.S. Army Materiel Command.
5. Mr. Douglas R. Newberry, Deputy to Commander, U.S. Army Tank-automotive and Armaments Command, U.S. Army Materiel Command.
6. Mr. Michael A. Parker, Deputy to Commander, U.S. Army Soldier and Biological Chemical Command, U.S. Army Materiel Command.
7. Ms. Kathryn T. Szymanski, Chief Counsel, U.S. Army Communications-Electronics Command, U.S. Army Materiel Command.
8. Dr. Clarence W. Kitchens, Jr., Principal Deputy for Technology, U.S. Army Materiel Command.
9. Ms. Renata F. Price, ADCS for RDA-Science, Technology and Engineering, U.S. Army Materiel Command.
10. Dr. Chine I. Chang, Director, Army Research Office.
11. Mr. Anthony A. LaPlaca, Director, Logistics & Readiness Center, U.S. Army Communications-Electronics Command, U.S. Army Materiel Command.
12. Mr. Robert Doto, Director, Intelligence and Information Warfare Directorate, U.S. Army Communications-Electronics Command, RDE Center, U.S. Army Materiel Command.
13. Mr. Dennis J. Turner, Director, Center for Software Engineering, U.S. Army Communications-Electronics Command RDE Center, U.S. Army Materiel Command.
14. Mr. James J. Barbarello, Director, C2 & Systems Integration Directorate, U.S. Army Communications-Electronics Command RDE Center.
15. Mr. Robert R. Lehnes, Deputy PEO-Communications Systems, Army Acquisition Executive PEO.
16. Mr. James L. Flinn III, Executive Director, Integrated Materiel Management Center, U.S. Army Aviation and Missile Command, U.S. Army Materiel Command.
17. Mr. Paul Bogosian, Deputy PEO-Aviation, Army Acquisition Executive PEO.
18. Mr. Barry J. Baskett, Director of Aviation Engineering, Aviation RDE Center, U.S. Army Materiel Command.
19. Ms. Vicky R. Armbruster, Deputy PEO-Tactical Missiles, Army Acquisition Executive PEO.
20. Dr. Larry O. Daniel, Director for System Engineering and Production, Missile RDE Center, U.S. Army Materiel Command.
21. Mr. Robert J. Spazzarini, Chief Counsel, U.S. Army Aviation and Missile Command, U.S. Army Materiel Command.
22. Mr. A.Q. Oldacre, Deputy PEO-Air and Missile Defense Army Acquisition Executive PEO.
23. Mr. Joseph T. Lehman, Deputy Director, Fire Support Center, U.S. Army Tank-automotive and Armaments Command, U.S. Army Materiel Command.
24. Mr. Jimmy C. Morgan, Director, Armament and Chemical Acquisition & Logistics Agency, U.S. Army Materiel Command.
25. Mr. Vemula P. Rao, Vice President for Customer Engineering, U.S. Army Tank-automotive and Armaments Command, U.S. Army Materiel Command.
26. Mr. Brian M. Simmons, Technical Director, U.S. Army Test and Evaluation Command, U.S. Army Materiel Command.
27. Mr. David J. Shaffer, Director, U.S. Army Materiel Systems Analysis Activity, U.S. Army Materiel Command.
28. Dr. Paul H. Dietz, Chief, Combat Integration Division, U.S. Army Materiel Systems Analysis Activity, U.S. Army Materiel Command.
29. Dr. Robert E. Singleton, Director, Engineering Sciences Directorate, U.S. Army Research Office.
30. Dr. James J. Wade, Director, Survivability, Lethality Analysis Directorate, U.S. Army Research Laboratory.

Gregory D. Showalter,
Army Federal Register Liaison Officer.

[FR Doc. 99–21540 Filed 8–18–99; 8:45 am]
BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Department of Army, Army Corps of Engineers

Notice of Intent to Prepare a Joint Environmental Impact Statement (EIS) and Environmental Impact Report (EIR) for the Proposed Rock Creek-Keefer Slough Flood Control Project, Butte County, CA

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

ACTION: Notice of intent.

SUMMARY: The U.S. Army Corps of Engineers (Corps), lead agency under the National Environmental Policy Act, intends to prepare a draft and final EIS/EIR evaluating the environmental effects of flood control and environmental restoration for the Rock Creek-Keefer Slough watershed in Butte County, California. The Corps is working with Butte County and the Rock Creek Reclamation District to provide this protection.

FOR FURTHER INFORMATION CONTACT: Questions about the proposed action and EIS/EIR can be answered by Steve Tuggle at (916) 557–6638 or by mail at U.S. Army Corps of Engineers, Planning Division, ATTN: Steve Tuggle, 1325 J Street, Sacramento, California 95814–2922.

SUPPLEMENTARY INFORMATION:

1. Project Location

The project area is located in Butte County approximately 90 miles north of Sacramento. The area of primary interest includes portions of the town of Nord and agricultural lands affected by flooding from Rock Creek and Keefer Slough. The streams of interest in this evaluation include portions of Rock Creek, Keefer Slough, Mud Creek, Pine Creek, Kusal Slough, and the Sacramento River. The project area is also interconnected within the Big Chico Creek Ecological Unit of the Butte Basin, a tributary of the Sacramento River. This project covers the area of Rock Creek and Keefer Slough between Highway 32 and ½ mile above the confluence of Rock Creek with the Anderson Branch of Rock Creek, all within Butte County.

2. Proposed Action and Alternatives

The Corps, in cooperation with the State of California (Department of Water Resources) and the local sponsor (Butte County), is conducting a feasibility investigation of the flood control and environmental restoration measures identified during the reconnaissance phase and described in the Rock Creek-Keefer Slough Initial Assessment dated February 1999. This feasibility investigation proposes to develop and evaluate alternative flood control and environmental restoration plans that would alleviate flooding for the 100-year storm event and enhance the existing environment along the Rock Creek-Keefer Slough system.

The feasibility report will address an array of alternatives and resource problems. Alternatives analyzed during the feasibility investigation will be a combination of one or more flood control and ecosystem restoration measures identified during the reconnaissance phase; additional measures maybe considered. These alternative measures include (1) setback levees and stream channel improvements, (2) environmental restoration measures, (3) bypass and diversion structures, and (4) detention storage measures.

The goal of this project is to provide the greatest environmental benefits possible in conjunction with the proposed flood control project. Primary objectives include reducing flood risk and property damages, preserving existing resources, improving water quality, restoring wetlands, increasing riparian and riverine habitat, and reducing cobble and sediment transport. Significant issues to be analyzed in depth in the EIS/EIR include appropriate levels of the flood damage reduction, adverse effects on vegetation and wildlife resources, special-status species, esthetics, cultural resources, recreation, and cumulative effects of related projects in the study area.

3. Scoping Process

''Scoping'' is a process to identify the actions, alternative, and effects to be evaluated in an environmental document. The project study plan provides for public scoping meeting and comments.

The Corps has initiated a process of involving Federal, State, and local agencies, and concerned individuals. After the draft EIS/EIR is prepared, a 45-day public review period will be provided for individuals and agencies to review and comment on the EIS/EIR. All interested parties should respond to this notice and provide a current address if they wish to be notified of the EIS/EIR circulation and future scoping meeting dates. Public meetings will be held to receive verbal and written comments. All comments will be considered and responded to in the final EIS/EIR.

4. Public Meetings

A public scoping meeting will be held in January 2000. Individuals are also encouraged to submit written scoping comments by December 31, 1999, to *http://www.buttecounty.net/publicworks/* or by mail to U.S Army Corps of Engineers, Planning Division, ATTN: Steve Tuggle, 1325 J Street, Sacramento, California 95814–2922.

5. Availability

The EIS/EIR is scheduled to be available for public review and comment in the summer of 2000.

Dated: August 9, 1999.

Michael J. Walsh,

COL, EN, Commanding.

[FR Doc. 99–21542 Filed 8–18–99; 8:45 am]

BILLING CODE 3710–EZ–M

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Proposed Information Collection; Chief of Naval Education and Training

AGENCY: Department of the Navy, DOD.

ACTION: Notice.

SUMMARY: The Chief of Naval Education and Training announces a proposed extension of an approved 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 18, 1999.

ADDRESSES: Send written comments and recommendations on the proposed information collection to LT D. Brown (OTE6/0813), 250 Dallas Street, Pensacola, FL 32508–5220.

FOR FURTHER INFORMATION CONTACT: To request additional information or to obtain a copy of the proposal and associated collection instruments, contact LT D. Brown at (850) 452–4941 (X319).

SUPPLEMENTARY INFORMATION:

Form Title and OMB Number: Application Forms Booklet, Naval Reserve Officers Training Corps Scholarship Program; OMB Control Number 0703–0026.

Needs and Uses: This collection of information is used to make a determination of an applicant's academic and/or leadership potential and eligibility for an NROTC scholarship. The information collected is used to select the best qualified candidates.

Affected Public: Individuals or households.

Annual Burden Hours: 56,000.

Number of Respondents: 14,000.

Responses per Respondent: 1.

Average Burden per Response: 4 hours.

Frequency: On occasion.

(Authority: 44 U.S.C. Sec. 3506(c)(2)(A))

Dated: August 12, 1999.

J.L. Roth,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 99–21551 Filed 8–18–99; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Proposed Information Collection; U.S. Marine Corps

AGENCY: Department of the Navy, DOD.

ACTION: Notice.

SUMMARY: The U.S. Marine Corps announces a proposed extension of an approved 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 18, 1999.

ADDRESSES: Send written comments and recommendations on the proposed information collection to Marine Corps Recruiting Command, (Code MROR), 3280 Russell Road, Quantico, VA 22134–5103.

FOR FURTHER INFORMATION CONTACT: To request additional information or to obtain a copy of the proposal and associated collection instruments, contact Gunnery Sergeant Ricardo Hudson at (703) 784–9449.

SUPPLEMENTARY INFORMATION:

Form Title and OMB Number: Personal Information Questionnaire; OMB Control No. 0703–0012.

Needs and Uses: The Personal Information Questionnaire is used to provide Headquarters, U.S. Marine Corps with a standardized method in rating officer program applicants in the areas of character, leadership, ability, and suitability for a service as a commissioned officer.

Affected Public: Individuals or households.

Annual Burden Hours: 8,350.

Number of Respondents: 16,700.

Responses per Respondent: 1.

Average Burden per Response: 30 minutes.

Frequency: On occasion.

(Authority: 44 U.S.C. Sec. 3506(c)(2)(A))

Dated: August 12, 1999.

J.L. Roth,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 99–21552 Filed 8–18–99; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The Leader, Information Management Group, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before September 20, 1999.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Danny Werfel, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW, Room 10235, New Executive Office Building, Washington, DC 20503 or should be electronically mailed to the internet address DWERFEL@OMB.EOP.GOV.

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 Leader, Information Management Group, Office of the Chief Information Officer, publishes that 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.

Dated: August 13, 1999.

William E. Burrow,

Leader, Information Management Group, Office of the Chief Information Officer.

Office of Elementary and Secondary Education

Title: Guidance to State Educational Agencies (SEAs) Seeking to Use an Alternative Method to Distribute Title I Funds to Local Education Agencies (LEAs) With Fewer Than 20,000 Total Residents.

Frequency: Guidance issued on as needed basis.

Affected Public: State, local or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 25.

Burden Hours: 200.

Abstract: Guidance for State educational agencies seeking to use an alternative method to distribute Title I Basic and Concentration Grants to local educational agencies.

Written comments and requests for copies of this information collection request should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 5624, Regional Office Building 3, Washington, DC. 20202–4651, or should be electronically mailed to the internet address *Vivian*__Reese@ed.gov, or should be faxed to 202–708–9346.

For questions regarding burden and/or the collection activity requirements, contact Kathy Axt at 703–426–9692. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Office of Elementary and Secondary Education

Title: Guidance to State Educational Agencies (SEAs) on Procedures for Adjusting ED-determined Title I Allocations to Local Educational Agencies (LEAs).

Frequency: Guidance issued on as needed basis.

Affected Public: State, local or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 52.

Burden Hours: 2,080.

Abstract: Guidance for State educational agencies on procedures for adjusting ED-determined Title I Basic and Concentration Grants allocations to local educational agencies to account for newly created LEAs and LEA boundary changes.

Written comments and requests for copies of this information collection request should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 5624, Regional Office Building 3, Washington, DC 20202–4651, or should be electronically mailed to the internet address *Vivian*__Reese@ed.gov, or should be faxed to 202–708–9346.

For questions regarding burden and/or the collection activity requirements, contact Kathy Axt at 703–426–9692. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 99–21502 Filed 8–18–99; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA No.: 84.015A and B]

Office of Postsecondary Education, Department of Education; Notice Inviting Applications for National Resource Centers Program for Foreign Language and Area Studies or Foreign Language and International Studies and Foreign Language and Area Studies Fellowships Program New Awards for Fiscal Year (FY) 2000

Purpose of Programs: The National Resource Centers (NRC) Program makes

awards to institutions of higher education for general assistance in strengthening nationally recognized centers of excellence in foreign language and area or international studies. NRC awards are used to support undergraduate centers or comprehensive centers, which include undergraduate, graduate, and professional school components.

The Foreign Language and Area Studies Fellowships (FLAS) Program makes awards to institutions of higher education for fellowship assistance to meritorious students undergoing graduate training in modern foreign languages and related areas or international studies. FLAS awards are used to support academic year and summer fellowships.

Eligible Applicants: Institutions of higher education and consortia of institutions of higher education.

Deadline for Transmittal of Applications: October 18, 1999.

Deadline for Intergovernmental Review: December 17, 1999.

Applications Available: September 7, 1999.

Available Funds: $21,230,000 for the NRC Program; and $15,090,000 for the FLAS Program. The estimated amount of funds available for new awards is based on the Administration's request for FY 2000. The actual level of funding, if any, is contingent on final congressional action.

Estimated Range of Awards: $175,000—$225,000 per year for the NRC Program, and $27,000—$172,800 per year for the FLAS Program.

Estimated Average Size of Awards: $193,000 for the NRC Program and $116,000 for the FLAS Program.

Estimated Number of Awards: 110 grants under the NRC Program, and 130 grants under the FLAS Program. It is anticipated that the 130 FLAS program grants will yield 600 academic year fellowships and 415 summer fellowships.

Note: The Department is not bound by any estimates in this notice.

Project Period: 36 months, beginning September 1, 2000.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 82, 85, and 86; and (b) The regulations for these programs as follows: 34 CFR parts 655 and 656 governing the NRC Program; and 34 CFR parts 655 and 657 governing the FLAS Program.

SUPPLEMENTARY INFORMATION:

FLAS Subsistence Allowance Level

The student subsistence allowance levels will be $11,000 for an academic year fellowship and $2,400 for a summer fellowship.

FLAS Institutional Payment

An institutional payment in lieu of tuition will be $10,000 for an academic year fellowship and $3,600 for a summer fellowship.

FLAS Travel Payment

Summer fellowships to be used on campuses other than the student's home institution may also include travel awards of $1,000 or the actual cost of travel, whichever is less.

FLAS budgets, therefore, should reflect $21,000 for each academic year fellowship requested, $6,000 for each summer fellowship requested, and summer travel awards, if requested.

Note: The amount of the award will not include allowances for dependents.

Absolute Priority

Under 34 CFR 75.105(c)(3) and 34 CFR 656.23(a)(1)–(2), and (4), the Secretary gives an absolute preference to applications that meet the following priority:

Projects that include teacher training activities on the language, languages, area studies, or general topic of the center.

Page Limit

The application narrative is where you, the applicant, address the selection criteria reviewers use in evaluating your application. You must limit the narrative to 35 double-spaced pages for a single institution's application or 45 double-spaced pages for a consortium's application using the following standards:

A ''page'' is 8.5″ × 11″, on one side only, with 1″ margins at the top, bottom, and both sides. You must double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions. However, you may single space charts, tables, figures or graphs.

If you use a proportional computer font, you may not use a font smaller than a 12-point font or an average character density greater than 18 characters per inch. If you use a nonproportional font or typewriter, you may not use more than 12 characters per inch.

The page limit does not apply to the cover sheet, the abstract, the budget section, or the appendices.

If, to meet the page limit, you use print size, spacing, or margins smaller than the standards in this notice, we will reject your application.

FOR APPLICATIONS OR INFORMATION CONTACT: Cheryl Gibbs, Ed McDermott, Karla Ver Bryck Block, or Amy Wilson, NRC–FLAS Team, U.S. Department of Education, International Education and Graduate Programs Service, 400 Maryland Avenue, S.W., Suite 600 Portals Building, Washington, D.C. 20202–5331. Telephone (202) 401–9798. The e-mail address for the NRC–FLAS Team is OPE__NRC-FLAS@ed.gov.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternate format (e.g., Braille, large print, audiotape, or computer diskette) on request to one of the contact persons listed in the preceding paragraph. Individuals with disabilities may obtain a copy of the application package in an alternate format, also, by contacting that person. However, the Department is not able to reproduce in an alternate format the standard forms included in the application package.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at either of the following sites:

http://ocfo.ed.gov/fedreg.htm

http://www.ed.gov/news/html

To use the PDF you must have the Adobe Acrobat Reader Program with Search, which is available free at either of the previous sites. If you have any questions about using the PDF, call the U.S. Government Printing Office (GPO) toll free, at 1–888–293–6498; or in the Washington, DC. area, at (202) 512–1530.

Note: The official version of a document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: http://www.access.gpo.gov/nara/index.html

Program Authority: 22 U.S.C. 1122.

Dated: August 16, 1999.

Claudio R. Prieto,

Acting Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 99–21626 Filed 8–18–99; 8:45 am]

BILLING CODE 4000–01–U

DEPARTMENT OF EDUCATION

[CFDA No.: 84.016A]

Office of Postsecondary Education, Undergraduate; International Studies and Foreign Language Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2000

Purpose of Program: The Undergraduate International Studies and Foreign Language Program provides grants to strengthen and improve undergraduate instruction in international studies and foreign languages in the United States.

Eligible Applicants: Institutions of higher education; combinations of institutions of higher education; partnerships between nonprofit educational organizations and institutions of higher education; and public and private non-profit agencies and organizations, including professional and scholarly associations.

Deadline for Transmittal of Applications: November 1, 1999.

Deadline for Intergovernmental Review: December 31, 1999.

Applications Available: September 7, 1999.

Available Funds: $1,990,000. The estimated amount of funds available for new awards under this competition is based on the Administration's request for this program for FY 2000. The actual level of funding, if any, is contingent on final congressional action.

Estimated Range of Awards: $40,000–$130,000.

Estimated Average Size of Awards: $71,071 per year.

Estimated Number of Awards: 28.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 24 months for grants to single institutions of higher education, and up to 36 months for grants to combinations of institutions of higher education and partnerships.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 82, 85, and 86; and (b) The regulations in 34 CFR parts 655 and 658.

SUPPLEMENTARY INFORMATION: Matching requirement: Under Title VI, Part A, section 604(a)(3)of the Higher Education Act of 1965, Undergraduate International Studies and Foreign Language grantees must provide matching funds in either of the following ways: (a) Cash contributions from the private sector equal to one-third of the total project costs; or (b) a combination of institutional and non-institutional cash or in-kind contributions equal to one-half of the total project costs. The Secretary may waive or reduce the required matching share for institutions that are eligible to receive assistance under part A or part B of title III or under title V of the Higher Education Act of 1965, as amended.

Priority

Under 34 CFR 75.105 (c)(2)(i), 34 CFR 658.35, and section 604(a)(5) of title VI of the Higher Education Act of 1965, as amended, the Secretary gives preference to applications that meet the following competitive priority. The Secretary awards five points to an application that meets this competitive priority. These points are in addition to any points the application earns under the selection criteria:

Applications from institutions of higher education or combinations of institutions that: (a) Require entering students to have successfully completed at least two years of secondary school foreign language instruction; (b) require each graduating student to earn two years of postsecondary credit in a foreign language or have demonstrated equivalent competence in the foreign language; or (c) in the case of a two-year degree granting institution, offer two years of postsecondary credit in a foreign language.

FOR APPLICATIONS OR INFORMATION CONTACT: Christine Corey, Undergraduate International Studies and Foreign Language Program, U.S. Department of Education, International Education and Graduate Programs Service, 400 Maryland Avenue, SW., Suite 600 Portals Building, Washington, DC 20202–5331. Telephone: 202–401–9783. The e-mail address for Ms. Corey is christine__corey@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternate format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact person listed in the preceding paragraph. Individuals with disabilities may obtain a copy of the application package in an alternate format, also, by contacting that person. However, the Department is not able to reproduce in an alternate format the standard forms included in the application package.

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http://ocfo.ed.gov/fedreg.htm
http://www.ed.gov/news/html

To use the PDF you must have the Adobe Acrobat Reader Program with Search, which is available free at either of the previous sites. If you have any questions about using the PDF, call the U.S. Government Printing Office (GPO) toll free, at 1–888–293–6498; or in the Washington, D.C. area, at (202) 512–1530.

Note: The official version of a document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: http://www.access.gpo.gov/nara/index.html

Program Authority: 20 U.S.C. 1124

Dated: August 16, 1999.

Claudio R. Prieto,

Acting Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 99–21627 Filed 8–18–99; 8:45 am]

BILLING CODE 4000–01–U

DEPARTMENT OF ENERGY

Idaho Operations Office; Notice of Availability of Solicitation for Awards of Financial Assistance

AGENCY: Idaho Operations Office, DOE.

ACTION: Notice of Availability of Solicitation Number DE–PS07–99ID13824.

SUMMARY: The U.S. Department of Energy (DOE) Idaho Operations Office (ID) is seeking applications for cost-shared research and development of technologies which will reduce energy consumption, reduce environmental impacts and enhance economic competitiveness of the domestic aluminum industry. The research is to address research priorities identified by the aluminum industry in the Aluminum Industry Technology Roadmap. This Roadmap can be found in the solicitation, which is available in its full text via the Internet at the following URL address: http://www.id.doe.gov/doeid/PSD/proc-div.html.

Potential benefits of the research must be realized in manufacturing processes, not in end-use applications. Approximately $6,500,000 in combined fiscal year 2000 and 2001 federal funds is expected to be available to totally fund the first year of selected research efforts. DOE anticipates making eight to twelve awards each with a duration of four years or less. Note: Additional funds of up to $3,000,000 may be

available specifically for Advanced Cell work (Primary Aluminum Production.) A minimum 50% non-federal cost-share is required for research and development projects. Multi-partner collaborations between industry, university, and National Laboratory participants are encouraged.

DATES: The issuance date of Solicitation Number DE–PS07–99ID13824 is on or about August 13, 1999. The deadline for receipt of full applications is November 4, 1999.

ADDRESSES: Applications should be submitted to: Seb Klein, Procurement Services Division, U.S. Department of Energy, Idaho Operations Office, 850 Energy Drive, Mail Stop 1221, Idaho Falls, Idaho 83401–1563.

FOR FURTHER INFORMATION CONTACT: Seb Klein, Contract Specialist at *kleinsm@id.doe.gov*, or Dallas Hoffer, Contracting Officer at hofferdl@id.doe.gov.

SUPPLEMENTARY INFORMATION: The statutory authority for the program is the Federal Non-Nuclear Energy Research and Development Act of 1974 (Pub. L. 93–577). The Catalog of Federal Domestic Assistance (CFDA) Number for this program is 81.086.

Issued in Idaho Falls on August 12, 1999.

R. J. Hoyles,

Director, Procurement Services Division.

[FR Doc. 99–21526 Filed 8–18–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER99–754–002]

AmerGen Energy Company, L.L.C.; Notice of Filing

August 13, 1999.

Take notice that on July 23, 1999, AmerGen Energy Company, L.L.C., tendered for filing a change in status with respect to its FERC Electric Tariff, Original Volume No. 1.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before August 23, 1999. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. 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. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222) for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–21487 Filed 8–18–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL99–84–000]

AmerGen Energy Company, L.L.C.; Notice of Filing

August 13, 1999.

Take notice that on July 23, 1999, AmerGen Energy Company, LLC (AmerGen), tendered for filing an application requesting the Federal Energy Regulatory Commission to waive the open access transmission tariff requirements of Order No. 888 and Section 35.28 of the Commission's Regulations, 18 CFR 35.28, and the OASIS requirements of Order No. 889.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before August 23, 1999. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. 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. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–21488 Filed 8–18–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP99–598–000]

Columbia Gas Transmission Corporation; Notice of Request Under Blanket Authorization

August 13, 1999.

Take notice that on August 6, 1999, Columbia Gas Transmission Corporation (Columbia), 12801 Fair Lakes Parkway, Fairfax, Virginia 22030–0146, filed in Docket No. CP99–598–000 a request pursuant to Sections 157.205 and 157.216 of the Commission's Regulations under the National Gas Act (18 CFR 157.205, 157.216) and Columbia's blanket certificate issued in docket No. CP83–76–000 to abandon three points of delivery to Columbia Gas of Ohio, Inc. (COH) and transfer ownership of 0.68 mile of 4-inch plastic piping to COH, all located in Jefferson County, Ohio. The application may be viewed on the web at www.ferc.fed.us. Call (202) 208–2222 for assistance.

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 therefore, 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. 99–21491 Filed 8–18–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2145–000 WS]

Public Utility District No. 1 of Chelan County; Notice of Public Utility District No. 1 of Chelan County's Request To Use Alternative Procedures in Filing a License Application

August 13, 1999.

On July 16, 1999, the existing licensee, Public Utility District No. 1 of Chelan County (Chelan PUD), filed a request to use the Commission's alternative procedures in submitting an application for a new license for the existing Rocky Reach Hydroelectric Project No. 2145. The 1,236.6-megawatt project is located on the Columbia River, about 7 miles upstream from the City of Wenatchee, Washington. Chelan PUD has demonstrated that it has made an effort to contact resource agencies, Indian tribes, nongovernmental organizations (NGOs), and others affected by the proposal, and that a consensus likely exists that the use of the alternative procedures is appropriate in this case. Chelan PUD has also submitted a communications protocol that was developed in consultation with interested entities.

The purpose of this notice is to invite comments on Chelan PUD's request to use the alternative procedures, pursuant to Section 4.34(i) of the Commission's regulations.[1] Additional notices seeking comments on the specific project proposal, interventions and protests, and recommended terms and conditions will be issued at a later date.

The alternative procedure being requested here combines the prefiling consultation process with the environmental review process, allowing the applicant to complete and file an Environmental Assessment (EA) in lieu of Exhibit E of the license application. This differs from the traditional process, in which the applicant consults with agencies, Indian tribes, and NGOs during preparation of the application for the license and before filing it, but the Commission staff performs the environmental review after the application is filed. The alternative procedures are intended to improve the licensing process by combining the prefiling consultation and environmental review processes into a single process, to facilitate greater participation, and to improve communication and cooperation among the participants.

Alternative Licensing Process and Rocky Reach Schedule

Chelan PUD has submitted a proposed schedule for the process that leads to the filing of a new license application by June, 2004. Study plans would be developed this summer through the end of the year for field work that would start in April, 2000. National Environmental Policy Act scoping would be conducted during early to mid 2000. Field-work would be conducted through summer 2002 (if needed), with a draft application and draft APEA to be issued for comment in the spring of 2003.

Comments

Interested parties have 30 days from the date of this notice to file with the Commission, any comments on Chelan PUD's proposal to use the alternative procedures to file an application for the Rocky Reach Hydroelectric Project.

Filing Requirements

The comments must be filed by providing an original and 8 copies as required by the Commission's regulations to: Federal Energy Regulatory Commission, Office of the Secretary, Dockets—Room 1A, 888 First Street, NE, Washington, DC 20426.

All comment filings must bear the heading ''Comments on the Alternative Procedures,'' and include the project name and number (Rocky Reach Hydroelectric Project No. 2145).

For further information on this process, please contact Vince Yearick of the Federal Energy Regulatory Commission at 202–219–3073 or E-mail vince.yearick@ferc.fed.us.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–21494 Filed 8–18–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ97–8–005]

South Carolina Public Service Authority; Notice of Filing

August 13, 1999.

Take notice that on July 28, 1999, South Carolina Public Service Authority filed revised standards of conduct in response to the Commission's July 1, 1999 Order on Standards of Conduct. 88 FERC ¶ 61,013 (1999).

Any person desiring to be heard or to protest the filings should file, in each particular proceeding and referencing the appropriate docket number, a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). All such motions to intervene or protest should be filed on or before August 27, 1999. 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 proceedings. Any person wishing to become a party to each proceeding must file a motion to intervene in each proceeding. Copies of these filings are on file with the Commission and are available for public inspection. These filings may also be viewed on the Internet at http://www.ferc.fed.us/online/htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc 99–21489 Filed 8–18–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2077–016]

USGen New England, Inc.; Notice Establishing Procedures for Relicensing and a Deadline for Submission of Final Amendments

August 13, 1999.

The license for the Fifteen Mile Falls Project No. 2077, located on the Connecticut River in Grafton County, New Hampshire, and Caledonia County, Vermont, will expire on July 31, 2001. On July 29, 1999, an application for new license was filed. The following is an approximately schedule and procedures that will be followed in processing the application:

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[1] Order No. 596, Regulations for the Licensing of Hydroelectric Projects, 81 FERC ¶ 61,103 (1997).

Date	Action
September 10, 1999	Commission notifies applicant that its application has been accepted and specifies the need for additional information and due date.
September 15, 1999	Commission issues public notice of the accepted application establishing dates for filing motions to intervene and protests.
September 30, 1999	Commission's deadline for applicant for filing a final amendment, if any, to its application.
September 30, 1999	Commission notifies all parties and agencies that the application is ready for environmental analysis.

Upon receipt of any additional information and the information filed in response to the public notice of the acceptance of the application, the Commission will evaluate the application in accordance with applicable statutory requirements and take appropriate action on the application.

Any questions concerning this notice should be directed to William Guey-Lee at (202) 219–2808, or email at william.gueylee@ferc.fed.us.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–21500 Filed 8–18–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP99–191–000]

Northern Natural Gas Company; Notice of Availability of the Environmental Assessment for the Proposed Elk River Loop '99 Project

August 13, 1999.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) on the natural gas pipeline facilities proposed by Northern Natural Gas Company (Northern) in the above-referenced docket. It also addresses alternative routes for the proposed pipeline.

The EA was prepared to satisfy the requirements of the National Environmental Policy Act. The staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major Federal action significantly affecting the quality of the human environment. The EA concludes there is an environmentally preferable alternative and requests comments about it.

The EA assesses the potential environmental effects of the construction and operation of about 15 miles of 16-inch-diameter pipeline loop and appurtenances in Anoka and Sherburne Counties, Minnesota.

The purpose of the proposed facilities would be to provide about 23,873 million British thermal units per day of natural gas to meet increased market demand served by Northern's Elk River Branchline. Minnegasco, a Division of NorAm Energy Corporation and Northern States Power Company—Minnesota have contracted with Northern for this incremental service.

The EA has been placed in the public files of the FERC. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference and Files Maintenance Branch, 888 First Street NE, Room 2A, Washington, DC 20426, (202) 208–1371.

Copies of the EA have been mailed to Federal, state and local agencies, public interest groups, landowners crossed by the proposed route or the alternatives, interested individuals, newspapers, and parties to this proceeding.

Any person wishing to comment on the EA may do so. To ensure consideration prior to a Commission decision on the proposal, it is important that we receive your comments before the date specified below. Please carefully follow these instructions to ensure that your comments are received in time and properly recorded:

- Send *two* copies of your comments to: Secretary, Federal Energy Regulatory Commission, 888 First St., NE, Room 1A, Washington, DC 20426;
- Label *one* copy of the comments for the attention of the Environmental Review and Compliance Branch, PR–112;
- Reference Docket No. CP99–191–000; and
- Mail your comments so that they will be received in Washington, DC on or before September 13, 1999.

Comments will be considered by the Commission but will not serve to make the commentor a party to the proceeding. Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).

The date for filing timely motions to intervene in this proceeding has passed. Therefore, parties now seeking to file late interventions must show good cause, as required by section 385.214(b)(3), why this time limitation should be waived Environmental issues have been viewed as good cause for late intervention. You do not need intervenor status to have your comments considered.

Additional information about the proposed project is available from Paul McKee in the Commission's Office of External Affairs, at (202) 208–1088 or on the FERC Internet website (www.ferc.fed.us) using the ''RIMS'' link to information in this docket number. Click on the ''RIMS'' link, select ''Docket #'' from the RIMS Menu, and follow the instructions. For assistance with access to RIMS, the RIMS helpline can be reached at (202) 208–2222.

Similarly, the ''CIPS'' link on the FERC Internet website provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings. From the FERC Internet website, click on the ''CIPS'' link, select ''Docket #'' from the CIPS menu, and follow the instructions. For assistance with access to CIPS, the CIPS helpline can be reached at (202) 208–2474.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–21490 Filed 8–18–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11574–000; Connecticut]

City of Norwich, Department of Public Utilities

Notice of Availability of Final Environmental Assessment

August 13, 1999.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380 (Order No. 486, 52 F.R. 47897), the Office of Hydropower Licensing has reviewed the application for an original minor license for the Occum Hydroelectric Project, located on the Shetucket River in New Loudon County, Connecticut, and has

prepared a Final Environmental Assessment (FEA) for the project.

Copies of the FEA are available in the Public Reference Branch, Room 2–A, of the Commission's offices at 888 First Street, NE, Washington, DC 20426. For further information, contact Ed Lee at (202) 219–2809.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–21497 Filed 8–18–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP99–584–000]

Koch Gateway Pipeline Company; Notice of Intent to Prepare an Environmental Assessment for the Proposed Index 301–08L2 Prichard Loop Project and Request For Comments On Environmental Issues

August 13, 1999.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the construction of about 3.9 miles of 24-inch-diameter mainline loop, proposed in the Index 301–08L2 Prichard Loop Project.[1] This EA will be used by the Commission in its decision-making process to determine whether the project is in the public convenience and necessity.

If you are a landowner receiving this notice, you may be contacted by a pipeline company representative about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The pipeline company would seek to negotiate a mutually acceptable agreement. However, if the project is approved by the Commission, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings in accordance with state law. A fact sheet addressing a number of typically asked questions, including the use of eminent domain, is attached to this notice as appendix 1.[2]

Summary of the Proposed Project

The Prichard Loop Project would be located entirely within the Prichard, Alabama city limits. Koch Gateway Pipeline Company (Koch) seeks authority to:

- Construct about 3.9 miles of 24-inch-diameter pipeline requiring about 31 acres of land;
- Use, as temporary workspace, about 12.4 acres of land;
- Construct a horizontal directional drill crossing of Chickasaw Creek;
- Use about 16 existing access roads; and
- At Whistler's Junction, replace the existing orifice meter with a 20-inch ultrasonic meter and install bypass and pigging facilities.

The location of the project facilities is shown in appendix 2. the proposed loop starts at Whistler's Junction (Station No. 11+95 on the Index 301–08L pipeline) and ties back into the mainline at Station No. 204+53, southwest of the Interstate 65 interchange with State Route 158. If you are interested in obtaining procedural information, please write to the Secretary of the Commission.

Land Requirements for Construction

About ninety-four percent of the proposed route of the Prichard Loop would occur within or adjacent to existing permanent rights-of-way of either Koch or the Alabama Power Company. Construction of the proposed facilities would require about 43.4 acres of land, including 14.2 acres of new permanent right-of-way. About 3.6 acres of existing pipeline and powerline rights-of-way would be used. The remaining 25.6 acres would be temporary construction areas (e.g., workspaces or construction right-of-way). All temporary construction areas would be allowed to revert to their former use.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and necessity. NEPA also requires us to discover and address concerns the public may have about proposals. We call this ''scoping''. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this Notice of Intent, the Commission requests public comments on the scope of the issues it will address in the EA. All comments received are considered during the preparation of the EA. State and local government representatives are encouraged to notify their constituents of this proposed action and encourage them to comment on their areas of concern.

The EA will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils.
- Water resources, fisheries, and wetlands.
- Vegetation and wildlife.
- Endangered and threatened species.
- Land use.
- Cultural resources.
- Public safety.

We will also evaluate possible alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Our independent analysis of the issues will be in the EA. Depending on the comments received during the scoping process, the EA may be published and mailed to Federal, state, and local agencies, public interest groups, interested individuals, affected landowners, newspapers, libraries, and the the Commission's official service list for this proceeding. A comment period will be allotted for review if the EA is published. We will consider all comments on the EA before we make our recommendations to the Commission.

To ensure your comments are considered, please carefully follow the instructions in the public participation section on page 4 of this notice.

Currently Identified Environmental Issues

We have already identified some issues that we think deserve attention based on a preliminary review of the proposed facilities and the environmental information provided by Koch. This preliminary list of issues may be changed based on your comments and our analysis.

- Four residences are located within 50 feet of the proposed construction right-of-way.
- The federally threatened gopher tortoise has been identified in the project area.
- Construction would include clearing 1.6 acres of forested wetlands.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. By becoming a commentor, your

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[1] Koch's application was filed with the Commission under Section 7 of the Natural Gas Act and Part 157 of the Commission's regulations.

[2] The appendices referenced in this notice are not being printed in the **Federal Register**. Copies are available from the Commission's Public Reference and Files Maintenance Branch, 888 First Street, N.E., Washington, D.C. 20426, or call (202) 208–1371. Copies of the appendices were sent to all those receiving this notice in the mail.

concerns will be addressed in the EA and considered by the Commission. You should focus on the potential environmental effects of the proposal, alternatives to the proposal (including alternative routes), and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be. Please carefully follow these instructions to ensure that your comments are received in time and properly recorded:

- Send two copies of your letter to: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First St., NE, Room 1A, Washington, DC 20426;
- Label one copy of the comments for the attention of the Environmental Review and Compliance Branch, PR–11.2;
- Reference Docket No. CP99–584–000; and
- Mail your comments so that they will be received in Washington, DC on or before September 13, 1999.

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an official party to the proceeding known as an ''intervenor''. Intervenors play a more formal role in the process. Among other things, intervenors have the right to receive copies of case-related Commission documents and filings by other intervenors. Likewise, each intervenor must provide 14 copies of its filings to the Secretary of the Commission and must send a copy of its filings to all other parties on the Commission's service list for this proceeding. If you want to become an intervenor you must file a motion to intervene according to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214) (see appendix 3). Only intervenors have the right to seek rehearing of the Commission's decision.

You do not need intervenor status to have your environmental comments considered. Additional information about the proposed project is available from Mr. Paul McKee of the Commission's Office of External Affairs at (202) 208–1088 or on the FERC website (www.ferc.fed.us) using the ''RIMS'' link to information in this docket number. Click on the ''RIMS'' link, select ''Docket #'' from the RIMS Menu, and follow the instructions. For assistance with access to RIMS, the RIMS helpline can be reached at (202) 208–2222.

Similarly, the ''CIPS'' link on the FERC Internet website provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings. From the FERC Internet website, click on the ''CIPS'' link, select ''Docket #'' from the CIPS menu, and follow the instructions. For assistance with access to CIPS, the CIPS helpline can be reached at (202) 208–2474.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–21492 Filed 8–18–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of an Amendment of License And Soliciting Comments, Motions to Intervene, and Protests

August 13, 1999.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Amendment of License.

b. *Project No.:* 184–060.

c. *Date Filed:* July 19, 1999.

d. *Applicant:* El Dorado Irrigation District (EID) and Pacific Gas & Electric Company (PG&E).

e. *Name of Project:* El Dorado Hydroelectric Project.

f. *Location:* On the South Fork American River and its tributaries, in El Dorado, Alpine, and Amador Counties, California. A large part of the project is located on more than 2,200 acres of federal land within the Eldorado National Forest.

g. *Filed Pursuant to:* 18 CFR 4.200.

h. *Applicant Contact:* Mr. William T. Hetland, El Dorado Irrigation District, 2890 Mosquito Rd, Placerville, CA 95667, (530) 622–4513, and Annette Fargalia, Esq., Pacific Gas & Electric Company, P.O. Box 7442, San Francisco, CA 94120, (415) 973–7145.

i. *FERC Contact:* Any questions on this notice should be addressed to Mohamad Fayyad at mohamad.fayyad@ferc.fed.us or 200–219–2665.

j. *Deadline for filing comments and/or motions:* September 20, 1999.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington DC 20426.

Please include the project number (184–060) on any comments or motions filed.

k. *Description of Filing:* EID proposes to reconstruct the El Dorado Diversion Dam and to construct a 1.8-mile-long bypass tunnel to replace a damaged portion of the existing El Dorado Canal. Both the diversion dam and the canal were severely damaged by storm runoff and land slides, which occurred during January 1997. Reconstruction of the dam would involve a headwall, replacement of a fish ladder, and an intake facility with a fish screen that would be reconstructed on the north side instead of the south side of the channel. The 1.8-mile-long bypass tunnel would replace about 2.3 miles of damaged wood and concrete portions of the canal. EID proposes to remove the damaged portions of the canal and to stabilize the portions that would remain unused following construction of the bypass tunnel.

l. *Location of the application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on the web at http://www.ferc.fed.us/online/rims.htm, (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item ''h'' above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the fling refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C.

20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–21493 Filed 8–18–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

August 13, 1999.

Take notice that the following two hydroelectric applications have been filed with the Commission and are available for public inspection:

a. *Application Type:* Non-Project Use of Lands and Waters.

b. *Project No.:* 1494–189, 1494–190, 1494–191, and 1494–193.

c. *Date Filed:* July 16, August 3, 1999 (1494–193).

d. *Applicant:* Grand River Dam Authority.

e. *Name of Project:* Pensacola.

f. *Location:* The Pensacola Project is located on the Grand (Neosho) River in Craig, Delaware, Mayes, and Ottawa Counties, Oklahoma. This project does not utilize Federal or Tribal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mary E. Von Drehle, Grand River Dam Authority P.O. Box 409, Vinita, OK 74301 (918) 256–5545.

i. *FERC Contact:* Any questions on this notice should be addressed to Jon Cofrancesco at Jon.Cofrancesco@ferc.fed.us or telephone 202–219–0079.

j. *Deadline for filing comments and or motions:* September 20, 1999.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, Mail Code: DLC, HL–11.1, 888 First Street, NE, Washington, DC 20426.

Please include the project number (1494–189, 1494–190, 1494–191, or 1494–193 on any comments or motions filed.

k. *Description of Project:* 1494–189 Grand River Dam Authority, licensee for the Pensacola Project, requests Commission authorization to issue a permit to Charles King, d/b/a Belle View Resort, to add one dock (32′×90′) containing 6 boat slips to an existing commercial facility, containing two docks with a total of 7 boat slips. The facility is located in Drowning Creek

1494–190 Grand River Dam Authority requests Commission authorization to issue a permit to James Baker, d/b/a Wolf's Landing, to add one dock (36′×191′) containing 13 boat slips to an existing commercial facility containing one dock with 12 boat slips, a swim dock, and two boat ramps. The facility is located in the upper end of Duck Creek.

1494–191 Grand River Dam Authority requests Commission authorization to issue a permit to Mack Magruder, d/b/a Hi-Lift Marina, to enlarge an existing commercial facility currently containing 3 primary docks with a total of 31 boat slips and one boat ramp. Mr. Magruder proposes to add 8 boat slips to an existing 7 boat slips and add one dock (76′×34′) containing 6 boat slips. The proposed additions would bring the total number of boat slips to 45. The facility is located in Drowning Creek.

1494–193 Grand River Dam Authority requests Commission authorization to issue a permit to Grand Lake Towne to add 10 boat slips and 6 personal watercraft slips to an existing commercial facility with two docks. The facility is located in Ketchum Cove.

l. *Locations of the application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on the web at www.ferc.fed.us. Call (202) 208–2222 for assistance. A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of rules of practice and procedure, 18 CFR 385.219, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the desired application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representative.

Linwood A. Watson, Jr.

Acting Secretary.

[FR Doc. 99–21495 Filed 8–18–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Surrender of License and Soliciting Comments, Motions to Intervene, and Protests

August 13, 1999.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Surrender of License.

b. *Project No.:* 2709–015.

c. *Date Filed:* July 16, 1999.

d. *Applicant:* Monongahela Power Company, The Potomac Edison Company, and West Penn Power Company.

e. *Name of Project:* Davis Pumped Storage Project.

f. *Location:* The project was proposed to be located on the Blackwater River

and Red Creek in Tucker County, West Virginia, and would have occupied federal lands within the Monongahela National Forest.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Thomas K. Henderson, Allegheny Energy, Inc., 10435 Downsville Pike, Hagerstown, MD 21740–1766, (301) 665–2703 and Mr. Stanley W. Legro, Verner, Liipfert, Bernhard, McPherson and Hand, Chartered, 901 15th Street, NW., Suite 700, Washington, DC 20005–2301, (202) 371–6000.

i. *FERC Contact:* Any questions on this notice should be addressed to James Hunter at (202) 219–2839, or e-mail address: james.hunter@ferc.fed.us.

j. *Deadline for filing comments and or motions:* September 20, 1999.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, Mail Code HL–11.1, 888 First Street, NE., Washington, DC 20426.

Please include the project number (P–2709–015) on any comments or motions filed.

k. *Description of Project:* The unconstructed project would have consisted of: (1) a 600-acre upper reservoir inundating the headwaters of Red Creek, formed by two rock-filled dams on the crest of Cabin Mountain; (2) an intake channel and a 1,325-foot-long tunnel through Cabin Mountain; (3) a 1,350-foot-long, 27-foot-diameter steel penstock; (4) two 1,670-foot-long, 19-foot-diameter steel penstocks; (5) four 520-foot-long, 13.5-foot-diameter steel penstocks; (6) a powerhouse containing four 250,000-kilowatt pump-turbine generating units; (7) a 500-foot-long tailrace channel; (8) a 7,000-acre lower reservoir formed by a rock-fill dam across the Blackwater River; and (9) appurtenant facilities.

The licensees request to surrender the license because they have not realized any economic benefit from the license.

l. *Locations of the application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on the web at http//www.ferc.fed.us/online/rims.htm (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the addresses in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Invervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of rules of practice and procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–21496 Filed 8–18–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests

August 13, 1999.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* New Major License.

b. *Project No.:* 2589–024.

c. *Date Filed:* July 29, 1999.

d. *Applicant:* Marquette Board of Light and Power.

e. *Name of Project:* Marquette Hydroelectric Project.

f. *Location:* On the Dead River near the city of Marquette, Marquette County, Michigan. The project does not use federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. David E. Hickey, Marquette Board of Light and Power, 2200 Wright Street, Marquette, MI 49855, (906) 228–0322.

i. *FERC Contact:* Any questions on this notice should be addressed to Lee Emery, E-mail address lee.emery@ferc.fed.us, or telephone 202–219–2779.

j. *Deadline for filing additional study requests:* September 27, 1999.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Status of environmental analysis:* This application is not ready for environmental analysis at this time.

l. *Description of the Project:* The project consists of the following two existing facilities: The Marquette Development No. 2 includes (1) Forestville Reservoir with a surface area of 110 acres and a storage volume of 2,900 acre-feet, impounded by (2) a 202-foot-long, 62-foot high, concrete-capped Cyclopean masonry dam with crest elevation 771.0 feet NGVD, which acts as a spillway under extremely high flows, with (a) a 197-foot-long concrete retaining wall, (b) a 75-foot-long training wall, and (c) a 33-foot-wide intake structure, with inclined trashracks, which discharges into (3) a 90-inch-diameter, wood-stave penstock, about 4,200 feet long, which conveys the water to (4) a concrete surge tank. From the surge tank, the water is carried by (5) two 440-foot-long, 78-inch-diameter steel penstocks to (6) Powerhouse No. 2, which is a 40-foot by 96-foot reinforced

concrete and brick structure containing (7) two, two-phase, 60-cycle horizontal turbine-generator sets with a combined generating capacity of 3,200 kilowatts, which transmit power to the 12,500 kV power distribution system.

The Marquette Development No. 3 includes (8) Tourist Park Reservoir with a surface area of 100 acres and a storage volume of 875 acre-feet, impounded by (9) a dam composed of (a) a 37-foot-long left spillway dike with a crest elevation of 642.84 feet NGVD, (b) an 80-foot long, 21-foot high, uncontrolled concrete ogee-shaped overflow spillway, with a crest elevation of 638.84 feet NGVD, (c) a gated spillway with two electric-hoist-operated, 10-foot-high by 10-foot-wide Taintor gates with a crest elevation of 629.84 feet NGVD, (d) a 758-foot-long right dike, with a reinforced concrete core wall with a crest elevation of 642.84 feet NGVD, and (e) a reinforced concrete intake structure with inclined trash racks, located 123 feet from the right end of the right dike, and having a single 20-foot-wide by 17-foot high bay. This bay controls water flowing into (10) an 8-foot-diameter, 150-foot long steel penstock, supported on nine reinforced-concrete pedestals spaced 16 feet apart, which carries water to (11) Powerhouse No. 3, which is a 28-foot by 40-foot reinforced concrete and brick structure containing (12) one two-phase, 60-cycle vertical turbine-generator set, which transmits power to the 12,500 kV power distribution system.

m. *Locations of the application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208–1371. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance. A copy is also available for inspection and reproduction at the address in item h above.

n. With this notice, we are initiating consultation with the State Historic Preservation Officer as required by § 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR at § 800.4.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–21498 Filed 8–18–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Non-Project Use of Project Lands and Waters and Soliciting Comments, Motions To Intervene, and Protests

August 13, 1999.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Non-Project Use of Project Lands and Waters.

b. *Project No.:* 2232–394.

c. *Date Filed:* June 10, 1999.

d. *Applicant:* Duke Energy Corporation.

e. *Name of Project:* Catawba-Wateree Hydroelectric Project.

f. *Location:* On Lake Hickory in the Mountain Creek Township, in Caldwell County, North Carolina. The project does not utilize federal or tribal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. E.M. Oakley, Duke Energy Corporation P.O. Box 1006 (EC12Y), Charlotte, NC 28201–1006 (704) 382–5778.

i. *FERC Contact:* Any questions on this notice should be addressed to Brian Romanek at (202) 219–3076, or e-mail address: brian.romanek@ferc.fed.us.

j. *Deadline for filing comments and or motions:* September 20, 1999.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, Mail Code: DLC, HL–11.1, 888 First Street, N.E., Washington, DC 20426.

Please include the project number (2232–394) on any comments or motions filed.

k. *Description of Proposal:* Duke Energy Corporation proposes to amend an existing lease with the 321 Marina by increasing the parcel size of leased project land from 1.1 to 1.448 acres to accommodate re-construction of existing boat slips and the construction of some additional boat slips. The 321 marina proposes to remove and rebuild six existing cluster piers now containing 36 slips and extend five of the piers to accommodate 38 additional slips, totaling 74 slips. No dredging is proposed.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, D.C. 20426, or by calling (202) 208–1371. This filing may be viewed on http://www.ferc.fed.us/online/rims.htm (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–21499 Filed 8–18–99; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6424–9]

National Environmental Justice Advisory Council Subcommittee on Health and Research Notification of Meeting and Public Comment Period; Open Meetings

Pursuant to the Federal Advisory Committee Act (FACA), Public Law 92–463, we now give notice that the National Environmental Justice Advisory Council (NEJAC) Subcommittee on Health and Research will meet on the dates and times described below. All times noted are Central Standard Time. All meetings are open to the public. Due to limited space, seating at the NEJAC meeting will be on a first-come basis. Documents that are the subject of NEJAC reviews are normally available from the originating EPA office and are not available from the NEJAC. The NEJAC Subcommittee meetings will take place at the Hyatt on Printer's Row, 500 S. Dearborn St. (312) 986–1234, Chicago, IL. The meeting dates are as follows: September 13, 1999 through September 15, 1999.

Registration for the meeting will begin on Monday, September 13, 1999 at 5 p.m. A public comment period to address community environmental health and health assessments is scheduled for Monday, September 13, 1999 from 6 p.m. to 9 p.m. The Subcommittee will convene Tuesday, September 14, 1999 from 9 a.m. to 5 p.m., and on Wednesday, September 15, 1999 from 8:30 a.m. to 4 p.m. Business will include discussion of community assessment protocols, the Community Environmental Assessment Decision Tree project, and the agenda for the May 2000 NEJAC meeting.

Any member of the public wishing additional information on the subcommittee meetings should contact the Designated Federal Official at the telephone number listed below.

Mr. Chen Wen—202/260–4109
Mr. Lawrence Martin—202/564–6497

Members of the public who wish to participate in the public comment period should register to do so by September 10, 1999. Individuals or groups making oral presentations during the public comment period should address their remarks to community environmental health and health assessments, and will be limited to a total time of five minutes. If you wish to submit written comments of any length (at least 15 copies), they should also be received by September 10, 1999. Comments received after that date will be provided to the Subcommittee as logistics allow. Correspondence concerning registration and written comments should be sent to Chen Wen at EPA/OPPTS, 401 M St. SW (7409), Washington, DC 20460.

Dated: August 14, 1999.

Lawrence Martin,

Designated Federal Official, National Environmental Justice Advisory Council Subcommittee on Health and Research.

[FR Doc. 99–21545 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6425–8]

Jack's Creek/Sitkin Smelting Superfund Site De Minimis Settlement; Proposed Administrative Settlement Under the Comprehensive Environmental Response, Compensation, and Liability Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: The United States Environmental Protection Agency is proposing to enter into a *de minimis* settlement pursuant to section 122(g)(4) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, (CERCLA), 42 U.S.C. 9622(g)(4). This proposed settlement is intended to resolve the liabilities under CERCLA of Robert J. Clark, d/b/a Clark Trucking, for response costs incurred by the United States Environmental Protection Agency at the Jack's Creek/Sitkin Smelting Superfund Site, Maitland County, Pennsylvania.

DATES: Comments must be provided on or before September 20, 1999.

ADDRESSES: Comments should be addressed to the Docket Clerk, United States Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania, 19103, and should refer to: In Re: Jack's Creek/Sitkin Smelting Superfund Site, Maitland County, Pennsylvania, U.S. EPA Docket No. III–98–094–DC.

FOR ADDITIONAL INFORMATION CONTACT: Daniel Isales (215) 814–2647, U.S. Environmental Protection Agency, Office of Regional Counsel, (3RC42), 1650 Arch Street, Philadelphia, Pennsylvania, 19103.

SUPPLEMENTARY INFORMATION:

Notice of De Minimis Settlement

In accordance with section 122(i)(1) of CERCLA, 42 U.S.C. 9622(i)(1), and section 7003(d) of the Solid Waste Disposal Act, 42 U.S.C. 6973(d), notice is hereby given of a proposed administrative settlement concerning the Jack's Creek/Sitkin Smelting Superfund Site in Maitland County, Pennsylvania. The administrative settlement was signed by the United States Environmental Protection Agency and is subject to review by the public pursuant to this Notice. The agreement has been approved by the Attorney General, United States Department of Justice, or her designee, pursuant to section 122(g)(4) of CERCLA, 42 U.S.C. 9622(g)(4). The Attorney General, or her designee, has also approved the agreement for the purpose of granting the covenant not to sue for damages to natural resources on behalf of the Department of the Interior (''DOI'').

The settling party has agreed to pay $2,000.00 to United States Environmental Protection Agency toward EPA response costs and $500.00 to DOI for damages to natural resources, subject to the contingency that the Environmental Protection Agency may elect not to complete the settlement based on matters brought to its attention during the public comment period established by this Notice.

EPA is entering into this agreement under the authority of sections 122(g) and 107 of CERCLA, 42 U.S.C. 9622(g) and 9607. Section 122(g) of CERCLA, 42 U.S.C. 9622(g), authorizes early settlements with *de minimis* parties to allow them to resolve their liabilities under, inter alia, section 107 of CERCLA, 42 U.S.C. 9607, to reimburse the United States for response costs incurred in cleaning up Superfund sites without incurring substantial transaction costs. The grant of a covenant not to sue for damages to natural resources by DOI to those parties paying their share of such allocated costs is subject to agreement in writing by DOI pursuant to section 122(j) of CERCLA, 42 U.S.C. 9622(j).

The Environmental Protection Agency will receive written comments upon this proposed administrative settlement for thirty (30) days from the date of publication of this Notice. Moreover, pursuant to section 7003(d) of the Solid Waste Disposal Act, 42 U.S.C. 6973(d), the public may request a meeting in the affected area. A copy of the proposed Administrative Order on Consent can be obtained by contacting Daniel Isales,

Office of Regional Counsel, at the address and phone number listed above.

W. Michael McCabe,

Regional Administrator, Region III.

[FR Doc. 99–21544 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6425–7]

Proposed Administrative Agreement for Collection of CERCLA Response and Oversight Costs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; proposed CERCLA 122(h) administrative agreement.

SUMMARY: EPA is proposing to execute an Administrative Agreement (Agreement) under section 122 of CERCLA for collection of a percentage of response and oversight costs at the King River Limited, Incorporated Superfund Site. The Respondent has agreed to pay $75,000 out of total unrecovered response and oversight costs of approximately $154,089.43, and in return will receive a covenant not to sue and contribution protection from EPA. EPA today is proposing to execute this Agreement because it achieves collection of a high percentage of total Site costs. The Respondent at the Site previously performed a Superfund removal under a CERCLA section 106 Unilateral Order, at a cost of approximately $7,000,000. Other responsible parties conducted removal activities at a cost of approximately $1,000,000. Thus, the overall value of the clean up and settlement to EPA is $8,075,000 out of an approximate total of $8,540,089.43. This is 99% of total Site costs.

DATES: Comments on this proposed settlement must be received on or before September 20, 1999.

ADDRESSES: Copies of the proposed settlement are available at the following address for review: (It is recommended that you telephone Sue Pastor at (312) 353–1325 before visiting the Region V Office). Sue Pastor, OPA (PI9–J), Coordinator, Office of Public Affairs, U.S. Environmental Protection Agency, Region V, 77 W. Jackson Boulevard (P–19J), Chicago, Illinois 60604, (312) 353–1325.

Comments on this proposed settlement should be addressed to: (Please submit an original and three copies, if possible) Sue Pastor, OPA (P19–J), Coordinator, Office of Public Affairs, U.S. Environmental Protection Agency, Region V, 77 W. Jackson Boulevard (P–19J), Chicago, Illinois 60604, (312) 353–1325.

FOR FURTHER INFORMATION CONTACT: Sue Pastor, Office of Public Affairs, at (312 353–1325.

SUPPLEMENTARY INFORMATION: The King River Limited Superfund Site is located at 202 Vine Street, New Boston, Ohio (Scioto County). In response to the release or threatened release of hazardous substances at or from the Site, EPA undertook response actions at the Site pursuant to section 104 of CERCLA, 42 U.S.C. 9604. The Site is a portion of a former steel mill approximately 6.74 acres in size which was contaminated in 1987 with polychlorinated biphenyls (PCBs) as a result of demolition activities conducted by Spar Construction. At the time of the demolition, Cyclops Corporation owned the Site and leased it to King River Limited. As a result of its 1992 merger with Cyclops Corporation, Armco Incorporated is a responsible party under section 107(a) of CERCLA, 42 U.S.C. 9607(a).

Pursuant to a December 29, 1993, Administrative Order on Consent, New Boston Industrial Corporation (''NBIC''), formerly known as King River Limited, conducted a site investigation at the Site, which included the sampling, excavation, and stockpiling of polychlorinated biphenyl (''PCB'')-contaminated soil. NBIC performed the cleanup work as agreed under the AOC until its available fund were exhausted.

Pursuant to a September 26, 1994, Unilateral Administrative Order, Armco maintained site security, transported and disposed of the stockpiled soils, and confirmed the removal of all PCB-contaminated soils containing PCBs over 25 ppm from the Site. In all, 388 rail cars carried approximately 35,000 tons of PCB-contaminated soils to a Toxic Substances Control Act (''TSCA'')-regulated landfill.

Costs associated with the cleanup of this Site, which were paid by responsible parties, were estimated to be over $8,000,000. EPA's total unrecovered oversight costs for this site are approximately $154,089.43.

A 30-day period, beginning on the date of publication, is open pursuant to section 122(I) of CERCLA for comments on the proposed Administrative Agreement. Comments should be sent to Sue Pastor of the Office of Public Affairs (P–19J), U.S. Environmental Protection Agency, Region V, 77 W. Jackson Boulevard, Chicago, Illinois 60604.

William E. Muno,

Director, Superfund Division.

[FR Doc. 99–21543 Filed 8–18–99; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 96–98; DA 99–1606]

Public Service Commission of Wisconsin's Petition Requesting Additional Authority To Implement Number Conservation Measures

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: On August 12, 1999, the Commission released a public notice requesting public comment on a petition from the Public Service Commission of Wisconsin (''Petition'') requesting additional authority to implement number conservation measures. The intended effect of this action is to make the public aware of, and to seek public comment on, this request.

DATES: Comments are due by September 13, 1999.

FOR FURTHER INFORMATION CONTACT: Jared Carlson at (202) 418–2320 or jcarlson@fcc.gov. The address is: Network Services Division, Common Carrier Bureau, Federal Communications Commission, The Portals, 445 12th Street, SW, Suite 6–A320, Washington, DC 20554. The fax number is: (202) 418–2345. The TTY number is: (202) 418–0484.

SUPPLEMENTARY INFORMATION:

On September 28, 1998, the Federal Communications Commission (''Commission'') released an order in the matter of a Petition for Declaratory Ruling and Request for Expedited Action on the July 15, 1997 Order of the Pennsylvania Public Utility Commission Regarding Area Codes 412, 610, 215, and 717, and Implementation of the Local Competition Provisions of the Telecommunications Act of 1996, *Memorandum Opinion and Order and Order on Reconsideration,* FCC 98–224, CC Docket No. 96–98, 63 FR 63613, NSD File No. L–97–42 (rel. September 28, 1998) (''Pennsylvania Numbering Order''). The Pennsylvania Numbering Order delegated additional authority to state public utility commissions to order NXX code rationing, under certain circumstances, in jeopardy situations and encouraged state commissions to seek further limited delegations of

authority to implement other innovative number conservation methods.

The Public Service Commission of Wisconsin (''PSCW'') has filed a request for additional delegation of authority to implement number conservation methods in their state. *See* Common Carrier Bureau Seeks Comment on the Public Service Commission of Wisconsin's Petition for Delegation of Additional Authority to Implement Number Conservation Measures, *Public Notice*, NSD File No. L–99–64, DA 99–1555 (rel. August 12, 1999).

The additional authority measures sought by the PSCW relate to issues under consideration in the *Numbering Resource Optimization Notice.* Numbering Resource Optimization, *Notice of Proposed Rulemaking*, CC Docket No. 99–200, FCC 99–122 (rel. June 2, 1999), 64 FR 32471. Because the PSCW faces immediate concerns regarding the administration of number resources in Wisconsin, we find it to be in the public interest to address this petition as expeditiously as possible, prior to completing the rulemaking proceeding.

We hereby seek comment on the issues raised in the PSCW's petition for delegated authority to implement various area code conservation measures. A copy of this petition will be available during regular business hours at the FCC Reference Center, Portals II, 445 12th Street, SW, Suite CY–A257, Washington, DC 20554, (202) 418–0267.

Interested parties may file comments concerning these matters on or before September 13, 1999. All filings must reference NSD File Number L–99–64 and CC Docket 96–98. Send an original and four copies to the Commission Secretary, Magalie Roman Salas, Portals II, 445 12th Street, SW, Suite TW–A325, Washington, DC 20554 and two copies to Al McCloud, Network Services Division, Portals II, 445 12th Street, SW, Suite 6A–320, Washington, DC 20554.

Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. Comments filed through the ECFS can be sent as an electronic file via the Internet to <http://www.fcc.gov/e-file/ecfs.html>. Generally, only one copy of an electronic submission must be filed. If multiple docket or rulemaking numbers appear in the caption of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rulemaking number referenced in the caption. In completing the transmittal screen, commenters should include their full name, Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to ecfs@fcc.gov, including ''get form <your e-mail address>'' in the body of the message. A sample form and directions will be sent in reply. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies.

This is a ''permit but disclose'' proceeding for purposes of the Commission's *ex parte* rules. *See generally* 47 CFR 1.1200–1.1216. As a ''permit but disclose'' proceeding, *ex parte* presentations will be governed by the procedures set forth in 1.1206 of the Commission's rules applicable to non-restricted proceedings. 47 CFR 1.1206.

Parties 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). Other rules pertaining to oral and written presentations are set forth in 1.1206(b) as well. For further information contact Jared Carlson of the Common Carrier Bureau, Network Services Division, at (202) 418–2320 or jcarlson@fcc.gov. The TTY number is (202) 418–0484.

Federal Communications Commission.

Blaise A. Scinto,

Deputy Chief, Network Services Division, Common Carrier Bureau.

[FR Doc. 99–21576 Filed 8–18–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice Required by the Y2K Act to Establish a Small Business Liaison

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Notice.

SUMMARY: Pursuant to section 18(b) of the Y2K Act, Public Law 106–37, 113 Stat. 185 (1999), the Federal Deposit Insurance Corporation is hereby designating Edward Silberhorn, Consumer Affairs Specialist, Division of Compliance and Consumer Affairs, as the point of contact to act as a liaison between the agency and insured state nonmember banks, as well as foreign banks having an insured branch, which qualify as small business concerns under the Act, with respect to problems arising out of Y2K failures and compliance with Federal rules or regulations. Mr. Silberhorn can be reached at (202) 942–3425.

FOR FURTHER INFORMATION CONTACT: Edward Silberhorn, Division of Compliance and Consumer Affairs, Federal Deposit Insurance Corporation, 550 17th Street, NW, Washington, D.C. 20429; telephone number: (202) 942–3425.

SUPPLEMENTARY INFORMATION: The Y2K Act defines ''small business concern'' as an unincorporated business, a partnership, corporation, association, or organization, with fewer than 50 full-time employees. In addition, the Y2K Act defines ''Y2K failure'' as failure by any device or system (including any computer system and any microchip or integrated circuit embedded in another device or product), or any software, firmware, or other set or collection of processing instructions to process, calculate, compare, sequence, display, store, transmit, or receive Year-2000 date-related data. This definition specifically includes failures to: (1) deal with or account for transitions or comparisons from, into, and between the years 1999 and 2000 accurately; (2) recognize or process accurately any specific date in 1999, 2000, or 2001; or (3) account accurately for the year 2000's status as a leap year, including recognition and processing of the correct date on February 29, 2000.

Small business concerns may contact the FDIC's small business liaison, as set forth above, effective August 19, 1999, through December 31, 2000.

In addition, as an alternative to contacting the FDIC's small business liaison in Washington, D.C., small business concerns may contact the following individuals in the Division of Compliance and Consumer Affairs in the FDIC's Regional Offices with their questions:

Atlanta, GA—James F. Pilkington, Community Affairs Officer, at 404–817–2515.

Boston, MA—Shirley P. Parish, Community Affairs Officer, at 781–794–5632.

Chicago, IL—Michael A. Frias, Community Affairs Officer, at 312–382–7506.

Dallas, TX—Eloy A. Villafranca, Community Affairs Officer, at 972–761–8010.

Kansas City, MO—Deanna S. Caldwell, Community Affairs Officer, at 816–234–8151.

Memphis, TN—David E. Wright, Community Affairs Officer, at 901–821–5295.

New York, NY—Valerie J. Williams, Community Affairs Officer, at 212–704–1245.

San Francisco, CA—Linda D. Ortega, Community Affairs Officer, at 415–978–0486.

Dated at Washington, D.C., this 13th day of August, 1999.

Federal Deposit Insurance Corporation.

James D. LaPierre,

Deputy Executive Secretary.

[FR Doc. 99–21507 Filed 8–18–99; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

PREVIOUSLY ANNOUNCED DATE AND TIME: Thursday, August 26, 1999, 10:00 a.m., Meeting Open to the Public.

THE OPEN MEETING HAS BEEN CHANGED TO: Wednesday, August 25, 1999, 10:00 a.m.

PERSON TO CONTACT FOR INFORMATION: Ron Harris, Press Officer, Telephone (202) 694–1220.

Mary W. Dove,

Acting Secretary of the Commission.

[FR Doc. 99–21711 Filed 8–17–99; 2:57 pm]

BILLING CODE 6715–01–M

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as Non-Vessel Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediaries pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. app. 1718 and 46 CFR 515).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel-Operating Common Carrier Ocean Transportation Intermediary Applicants

Charter Container Line, Inc., 842 Clifton Avenue, Suite 1, Clifton, NJ 07013, Officers: Joseph R. Cuccurullo, President (Qualifying Individual), Patrick Costin, Vice President

Continental Container Line, Inc., 182–16 147th Avenue, Jamaica, NY 11413, Officers: Sai K. Ng, Vice President (Qualifying Individual), Nick Lin, Vice President

Global Cargo U.S.A., Inc., 9111 NW 105th Way, Medley, FL 33178, Officers: Jose Cordo, Secretary (Qualifying Individual), Geoffredo Holbik, President

Gramter International (U.S.A.) Co., Ltd., 11222 La Cienega Blvd., Suite 358, Inglewood, CA 90304, Officers: Johnny Liu, President (Qualifying Individual), Jenny Chen, Secretary

Korea Express Atlanta, Inc., 5559 New Peachtree Road, Chamblee, GA 30341, Officer: Un Kil An, President (Qualifying Individual)

Lafawa Inc., 358 Victoria Street, San Francisco, CA 94132, Officers: Charlie Shi, Director (Qualifying Individual), Xiao Yan Gu, Chief Executive Officer

S. R. International, Inc., 289 E. Redondo Beach Blvd., Gardena, CA 90248, Officers: Soon Yeon Lim, Chief Financial Officer (Qualifying Individual), Han K. Kim, President

Sunlight Transport, Inc., 139 Mitchell Avenue, Suite 229, South San Francisco, CA 94080, Officer: Young Suk S. Waller, President (Qualifying Individual)

Valley Freight Consolidators, Inc., 2025 N.W. 102nd Avenue, Unit 109, Miami, FL 33172, Officer: Jose Rodrico Rincon, President (Qualifying Individual)

Trans-Jam Express Shipping Co., 479 Rogers Avenue, Brooklyn, NY 11225, Dwight Wisdom, Sole Proprietor

Global Shipping, Inc., Parkway One, Suite 201, 2697 International Parkway, Virginia Beach, VA 23452, Officer: R. Timothy Jones, Vice President (Qualifying Individual)

Pacific & Atlantic Ocean Container Line Inc., 45 Rockefeller Plaza, Suite 3162, New York, NY 10020, Officer: Oscar Anthony Poli, Exec. Vice President (Qualifying Individual)

Pan Star Express (Chicago) Corp., 228 Howard Street, Des Plaines, IL 60018, Officer: Ivy S. Wang, Chief Financial Officer (Qualifying Individual)

Pan-World Express, Inc., 5359 W. Valley Boulevard, Los Angeles, CA 90032, Officer: Adam D. Lam, President (Qualifying Individual)

Dit (USA), Inc., 1805 W. Hovey, Suite B, Normal, IL 61761, Officer: Mark Boulware, Assistant Secretary (Qualifying Individual)

Trans Service Line (USA), Inc., 50 Broadway, Suite 1603, New York, NY 10004, Officer: Jean-Francois Pinson, President (Qualifying Individual)

China United Transport, Inc., 2063 South Atlantic Blvd., Suite 2–B, Monterey Park, CA 91754, Officer: Xuexiang Li, President (Qualifying Individual)

Delta Line International, Inc., 9164 NW 150 Terrace, Miami, FL 33018, Officer: Ana M. Vega, President (Qualifying Individual)

Amos Cargo Service, Inc., 901 W. Victoria Street, Unit B–2, Compton, CA 90220, Officer: Chong W. Kim, President (Qualifying Individual)

Oconca Shipping (LAX) Inc., 229 S. Glasgow Avenue, Inglewood, CA 90301, Officer: Mimi Mak, President (Qualifying Individual)

TDC International Express, Inc., 2118 Sunny Ridge Place, Fullerton, CA 92833, Officer: Susan Cha, President (Qualifying Individual)

Caretrans Freight Service, Inc., 500–A North Nash Street, El Segundo, CA 90245, Officers: Basal K. Lau, Secretary (Qualifying Individual), William Chiao, President

Global Consolidation Services, LLC, 200 Middlesex Avenue, Carteret, NJ 07008, Officer: Charles Centorrino, President (Qualifying Individual)

Non-Vessel-Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicants

U.S. Intermodal Maritime, Inc., 12610 Interurban Ave., So., Bldg. #D, Tukwila, WA 98168, Officer: Ian Seok Moon, President (Qualifying Individual)

Servi-Fast International Corp., 10400 N.W. 33rd Street, Suite #120, Miami, FL 33172, Officers: Cesar A. Baez, Vice President (Qualifying Individual), Carlos M. Alvarez, President

EMO Trans Georgia, Inc., 20 Southwoods Pkwy., Suite 500, Atlanta, GA 30354, Officer: Olen Wood, Vice President (Qualifying Individual)

Transportation Bureau of Baltimore, Inc., d/b/a TBB Global Logistics, 11350 McCormick Road, Executive Plaza I, Suite 305, Hunt Valley, MD 21031, Officers: Shiron Kessler Paul, Int'l. Operations Officer (Qualifying Individual), Jay M. Polakoff, Chairman of the Board

Ocean Freight Forwarders—Ocean Transportation Intermediary Applicants

International Warehouse Services, Inc., 3400 McIntosh Road, P.O. Box 21031, Ft. Lauderdale, FL 33335, Officers: Bettina Hoyer, Secretary (Qualifying Individual), Fred C. Roqacki, President

Dated: August 13, 1999.

Ronald D. Murphy,

Assistant Secretary.

[FR Doc. 99–21480 Filed 8–18–99; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Agency information collection activities: Announcement of Board approval under delegated authority and submission to OMB

AGENCY: Board of Governors of the Federal Reserve System

SUMMARY:

Background. Notice is hereby given of the final approval of proposed information collection 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). Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the OMB 83-Is and supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. 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. West--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, without revision of the following report:

1. Report title: Recordkeeping, Reporting, and Disclosure Requirements in Connection with Regulation BB (Community Reinvestment).

Agency form number: unnum Reg BB.

OMB Control number: 7100-0197.

Frequency: Annual.

Reporters: State Member Banks.

Annual reporting hours: 151,680 hours.

Estimated average hours per response: Small business and small farm loan register: 219 hours; Consumer loan data: 326 hours; Other loan data: 25 hours; Assessment area delineation: 2 hours; Small business and small farm loan data: 8 hours; Community development loan data: 13 hours; HMDA out of MSA loan data: 253 hours; Data on lending by a consortium or third party: 17 hours; Affiliate lending data: 38 hours; Strategic plan: 275 hours; Request for designation as a wholesale or limited purpose bank: 4 hours; and Public file: 10 hours.

Number of respondents: Public file: 989; Small business and small farm loan register, Assessment area delineation, Small business and small farm loan data, Community development loan data, and HMDA out of MSA loan data: 227; Consumer loan data: 77; Other loan data: 50; Data on lending by a consortium or third party: 11; Affiliate lending data: 32; Strategic plan: 6; and Request for designation as a wholesale or limited purpose bank: 5. Small businesses are affected.

General description of report: The recordkeeping, reporting, and disclosure requirements associated with Regulation BB are authorized by the Federal Reserve Act (12 U.S.C. § 248) and the Community Reinvestment Act (12 U.S.C. § 2901 *et seq.*) and are mandatory to evidence compliance. Generally, the data that are reported to the Federal Reserve are not considered confidential.

Abstract: The Community Reinvestment Act (CRA) and Regulation BB encourage financial institutions to help meet the credit needs of their entire communities, consistent with safe and sound banking practices. The information collection associated with CRA and Regulation BB applies to state member banks, although not all are required to submit data to the Federal Reserve. The requirements imposed on the institutions are based primarily on the asset size of the institutions and whether an institution elects to comply with the optional reporting and recordkeeping requirements.

State member banks (SMBs) must delineate an assessment area(s) and larger banks (as defined in Regulation BB) must provide a list of the geographies within this area(s) to the Federal Reserve. State member banks must keep a public file of required information. The public file requirements are slightly different for small banks (as defined in Regulation BB) or banks that were small banks during the prior calendar year than for banks other than small banks. SMBs must display a public notice in the lobby of the main office and each branch informing consumers about the availability of certain CRA information. Banks other than small banks (large banks) must maintain data on small business and small farm loans; small banks may elect to maintain information on those loans. Large banks must report aggregated data on small business and small farm loans and on community development loans. While Regulation C requires certain institutions to report Home Mortgage Disclosure Act loan data and maintain information on those loans, CRA additionally requires large banks that are HMDA reporters to identify the location of each home mortgage loan application, origination, or purchase outside the MSAs where the institution has offices or outside any MSA. Any bank may elect to collect and maintain records on consumer loans and other loan data for consideration under the lending test. Also, any bank may collect, maintain, and report data on lending by affiliates or a consortium/third party with which it is involved. A bank that wishes to be evaluated under its own strategic plan must submit that plan to the Federal Reserve and must operate under it for at least one year before being evaluated under it. A bank that wishes to be designated as a wholesale or limited purpose bank must make that request in writing.

Current Actions: In May 1999 the Federal Reserve along with the Office of Comptroller of the Currency (OCC), and the Federal Deposit Insurance Corporation (FDIC), and Office of Thrift Supervision (OTS) published a joint notice in the *Federal Register*, requesting comment on their intent to extend the information collections for their CRA regulations. Pursuant to 5 CFR 1320.16, this was an initial notice and request for comment for the Federal Reserve; it was a final notice for the other agencies. The agencies' request for OMB review involved a reestimate of burden but no change in the underlying information collections.

All four agencies received four public comment letters from banking trade associations and one from a community interest group. The FDIC and the OCC each received two letters from financial institutions. This final notice addresses all the comment letters received by the four agencies.

The community interest group commented that the benefits of increased lending to underserved populations outweigh the costs and that the burden estimates for large banks are overstated. The four financial institutions commented that the burden estimates were low and three provided estimates of their own burden for CRA. All four banking trade associations commented that the new burden estimates are still too low, although two acknowledged that the they are improved. The four agencies recognize that their CRA regulations impose significant regulatory burden on depository institutions, and they appreciate the commenters' efforts to provide additional input. Although the estimates may not necessarily represent

the time spent by any particular institution, the agencies believe that the burden estimates fairly represent the total burden on the industry as a whole.

Three of the trade associations and two of the financial institutions commented on the specific requirements that are included in the burden estimates. The Federal Reserve's OMB supporting statement provides a detailed list of the elements included in the burden estimate. Two trade associations and one bank questioned whether the collection of information is necessary for the proper performance of the functions of the agency and is the least burdensome alternative. The community interest group expressed the opposite view, that the agencies cannot assess CRA performance without these data collection requirements. The justification for this information collection and its use by the Federal Reserve are also addressed in the OMB supporting statement. Some commenters questioned the methodology used for estimating the burden. As mentioned in the May 1999 *Federal Register* notice, the agencies combined the information from several sources, including public comments, contacts with CRA respondents, and knowledgeable agency staff, to derive the burden estimates.

In addition to addressing the paperwork requirements of CRA, several commenters discussed broader issues, including regulatory and examination burden. One banking trade association also included recommendations addressed to OMB. These issues are not addressed here as they are not appropriate for this notice.

Board of Governors of the Federal Reserve System, August 13, 1999.

Jennifer J. Johnson

Secretary of the Board.

[FR Doc. 99–21481 Filed 8–18–99; 8:45am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities: Proposed Collections; Comment Request

The Department of Health and Human Services, Office of the Secretary will periodically publish summaries of proposed information collections projects and solicit public comments in compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request more information on the projects or to obtain a copy of the information collection plans and instruments, call the OS Reports Clearance Officer on (202) 690–6207.

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 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.

Proposed Project 1

Research on Employment Supports for People with Disabilities—NEW—The Office of the Assistant Secretary for Planning and Evaluation has embarked on a project to collect extensive information on the experiences of people with disabilities in competitive employment. As part of this effort they intend to conduct a series of discussions with working people with disabilities across three locations in the United States and Canada for the purpose of gaining detailed information on their employment experiences. *Respondents:* Individuals or households—Reporting Burden Information for Screener—*Number of Respondents:* 750; *Burden per Response:* 7 minutes; *Total Burden for Screener:* 88 hours—Burden Information for Focus Group Registration—*Number of Respondents:* 375; *Burden per Response:* 10 minutes; *Total Burden of Registration:* 63 hours—Burden Information for Focus Group—*Number of Respondents:* 375; *Burden per Response:* 150 minutes; *Total Burden for Focus Group:* 938—Burden Information for Post-Focus Group Evaluation—*Number of Respondents:* 375; *Burden per Response:* 7 minutes; *Total Burden for Evaluation:* 44 hours—*Total Burden:* 1,133 hours.

Send comments to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201. Written comments should be received within 60 days of this notice.

Dated: August 12, 1999.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 99–21483 Filed 8–18–99; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities: Submission for OMB Review; Comment Request

The Department of Health and Human Services, Office of the Secretary publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and 5 CFR 1320.5. The following are those information collections recently submitted to OMB.

Proposed Projects 1. Cash and Counseling Demonstration—Additional Survey Instruments—New—

Cash and Counseling is a consumer directed care model for individuals with physical or developmental disabilities. A demonstration project implementing this model is being evaluated by the Office of the Assistant Secretary for Planning and Evaluation. This portion of the evaluation consists of four information collection instruments. Respondents: Individuals or Households, For-profit, Non-profit Institutions; Burden Information for Informal Caregiver Survey—Number of Respondents: 8,000; Burden per Response: .38 hours; Total Burden for Informal Caregiver Survey: 3,040 hours—Burden Information for Paid Worker Survey—*Number of Respondents:* 800; *Burden per Response:* .5 hours; *Total Burden for Paid Worker Survey:* 400 hours—Burden Information for Consultant Survey—*Number of Respondents:* 400; *Burden per Response:* .58 hours; *Total Burden for Consultant Survey:* 200 hours—Burden Information for Ethnographic Discussion Guide—*Number of Respondents:* 300; *Burden per Response:* 1 hours; *Total Burden for Ethnographic Discussion Guide:* 300 hours—*Total Burden:* 3,940 hours. *OMB Desk Officer:* Allison Eydt.

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690–6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW, Washington, DC, 20201. Written comments should be received within 30 days of this notice.

Dated: August 11, 1999.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 99–21482 Filed 8–18–99; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry

[Program Announcement 00017]

Public Health Conference Support Grant Program (Includes HIV Prevention); Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) announce the availability of fiscal year (FY) 2000 funds for a grant program for Public Health Conference Support (Includes HIV Prevention). This program addresses the following ''Healthy People 2000'' priority area(s) for CDC and ATSDR, with the exceptions of Mental Health, and Substance Abuse.

CDC priority areas are; Physical Activity and Fitness; Nutrition; Tobacco; Violent and Abusive Behavior; Unintentional Injuries; Occupational Safety and Health; Environmental Health; Oral Health; Maternal and Infant Health; Heart Disease and Stroke; Cancer; Diabetes and Chronic Disabling Conditions; Sexually Transmitted Diseases; Human Immunodeficiency Virus (HIV), and Immunization and Infectious Disease. Conferences on Mental Health and Substance Abuse should be directed to other Federal Agencies.

The purpose of conference support funding is to provide PARTIAL support for specific non-federal conferences in the areas of health promotion and disease prevention information and education programs, and applied research.

Because conference support by CDC/ATSDR creates the appearance of CDC/ATSDR co-sponsorship, there will be active participation by CDC/ATSDR in the development and approval of the conference agenda. CDC/ATSDR funds will be expended only for approved portions of the conference.

The mission of CDC is to promote health and quality of life by preventing and controlling disease, injury, and disability.

CDC supports local, State, academic, national, and international health efforts to prevent unnecessary disease, disability, and premature death, and to improve the quality of life. This support often takes the form of education, and the transfer of high quality research findings and public health strategies and practices through symposia, seminars, and workshops. Through the support of conferences and meetings in the areas of public health research, education, prevention research in program and policy development in managed care and prevention application, CDC is meeting its overall goal of dissemination and implementation of new cost-effective intervention strategies.

ATSDR priority areas are: (1) health effects of hazardous substances in the environment; (2) disease and toxic substance exposure registries; (3) hazardous substance removal and remediation; (4) emergency response to toxic and environmental disasters; (5) risk communication; (6) environmental disease surveillance; and (7) investigation and research on hazardous substances in the environment.

The mission of ATSDR is to prevent exposure and adverse human health effects and diminished quality of life associated with exposure to hazardous substances from waste sites, unplanned releases, and other sources of pollution present in the environment.

ATSDR's systematic approaches are needed for linking applicable resources in public health with individuals and organizations involved in the practice of applying such research. Mechanisms are also needed to shorten the time frame between the development of disease prevention and health promotion techniques and their practical application. ATSDR believes that conferences and similar meetings that permit individuals to engage in hazardous substances and environmental health research, education, and application (related to actual and/or potential human exposure to toxic substances) to interact, are critical for the development and implementation of effective programs to prevent adverse health effects from hazardous substances.

B. Eligible Applicants

Applications for CDC support may be submitted by public and private non-profit organizations. Public and private non-profit entities include but are not limited to State and local governments or their bona fide agents, voluntary associations, foundations, civic groups, scientific or professional associations, universities, and Federally-recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

ONLY Conferences planned for May 01, 2000 through April 30, 2001 are eligible to apply under this announcement.

Note: Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

Applications for ATSDR support may be submitted by the official public health agencies of the States, or their bona fide agents. This includes the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, the Virgin Islands, the Federated States of Micronesia, Guam, the Northern Mariana Islands, the Republic of the Marshall Island, the Republic of Palau, and Federally-recognized Indian Tribal governments. State organizations, including State universities, State colleges, and State research institutions must establish that they meet their respective State's legislature definition of a State entity or political subdivision to be considered an eligible applicant. Also eligible are nationally recognized associations of health professionals and other chartered organizations generally recognized as demonstrating a need for information to protect the public from the health effects of exposure to hazardous substances.

C. Availability of Funds

Approximately $900,000 is available from CDC in FY 2000 to fund approximately 35 to 45 awards. It is expected that the average award will be $20,000. Funding estimates may change. For FY 2000 awards will be made for three cycles A, B & C each for a 12-month budget period within a 12-month project period. See (Appendix 3) for suggested dates of when to apply for funds. No awards will be made during a cycle between the LOI due date and the Award Date unless approved by the awarding office.

State and local health departments applying for HIV prevention conference support funds may only apply under Category 2 (See Appendix 4 Applications Content for HIV Applicants).

Approximately $50,000 is available from ATSDR in FY 2000 to fund approximately six awards. It is expected

that the average award will be $8,000, ranging from $5,000 to $10,000. It is expected that the awards will begin on or about thirty days before the date of the conference and will be made for a 12-month budget period within a 12-month project period. Funding estimates may change.

Use of Funds

a. CDC and ATSDR funds may be used for direct cost expenditures: Salaries; speaker fees (for services rendered); rental of necessary conference related equipment; registration fees; and transportation costs (not to exceed economy class fare) for non-Federal individuals.

b. CDC and ATSDR funds may be used for only those parts of the conference specifically supported by CDC or ATSDR as documented in the grant award.

c. CDC and ATSDR funds may NOT be used for the purchase of equipment; payments of honoraria (for conferring distinction); alterations or renovations; organizational dues; support entertainment or personal expenses; food or snack breaks; cost of travel and payment of a Federal employee; per diem or expenses other than local mileage for local participants. Travel for CDC/ATSDR employees will be supported by CDC/ATSDR. Travel for other Federal employees will be supported by their respective agencies. When certain meals are an integral and necessary part of a conference (i.e., working meal where business is transacted and/or a bonafide business product is produced), grant funds may be used for such meals (Where meals and/or lodgings are furnished without charge or at a nominal cost, e.g., as part of the registration fee, the proposed per diem or subsistence allowance will take this into consideration.).

d. CDC and ATSDR funds may NOT be used for reimbursement of indirect costs.

e. CDC and ATSDR will NOT fund 100 percent of any conference proposed under this announcement. Part of the cost of the proposed conference must be supported with other than Federal funds.

f. CDC and ATSDR will NOT fund a conference after it has taken place.

g. Although the practice of handing out novelty items at meetings is often employed in the private sector to provide participants with souvenirs, Federal funds cannot be used for this purpose.

Funding Preference

For HIV Applicants Only

Preference may be given to:

a. Conferences sponsored by organizations that serve high-risk populations especially populations and geographic areas that are under-served.

b. Applications consistent with the CDC national goal of assisting in building and maintaining State, local, and community infrastructure and technical capacity to carry out necessary HIV and STD prevention programs.

No preference will be given to organizations that have received funding in past years.

D. Program Requirements

CDC and ATSDR grantees must meet the following requirements:

1. The conference organizer(s) may use CDC's/ATSDR's name only in factual publicity for the conference and should understand that CDC/ATSDR involvement in the conference does not necessarily indicate support for the organizer's general policies, activities, or products or the content of speakers' presentations.

2. Any conference sponsored by CDC shall be held in facilities that are fully accessible to the public as required by the Americans with Disabilities Act Accessibility Guidelines (ADAAG). Accessibility under ADAAG addresses accommodations for persons with sensory impairments as well as persons with physical disabilities or mobility limitations. The Director, or his/her designee, of the CIO(s) providing funds or approving CDC sponsorship of a conference must assure that the proposed meeting facilities comply with ADAAG.

3. Manage all activities related to program content (e.g., objectives, topics, attendees, session design, workshops, special exhibits, speaker's fees, agenda composition, and printing). Many of these items may be developed in concert with assigned CDC or ATSDR project personnel.

4. Provide draft copies of the agenda and proposed ancillary activities to CDC or ATSDR for approval. All but 10% of the total funds awarded for the proposed conference will be restricted pending approval of a full final agenda by CDC or ATSDR. The remaining 90% of funds will be released by letter to the grantee upon that approval. CDC and ATSDR reserve the right to terminate co-sponsorship at any time.

5. Determine and manage all promotional activities (e.g., title, logo, announcements, mailers, press, etc.). CDC or ATSDR must review and approve any materials with reference to CDC or ATSDR involvement or support.

6. Manage all registration processes with participants, invitee, and registrants (e.g., travel, reservations, correspondence, conference materials and handouts, badges, registration procedures, etc.).

7. Plan, negotiate, and manage conference site arrangements, including all audio-visual needs.

8. If the proposed conference is or includes a satellite broadcast:

(i) Provide individual, on-camera rehearsals for all presenters,

(ii) Provide at least one full dress rehearsal involving the moderator, all presenters, equipment, visuals, and practice telephone calls at least one day before the actual broadcast and as close to the actual broadcast time as possible,

(iii) Provide full scripting and Teleprompter use for the moderator and all presenters,

(iv) Select a professional moderator. Analyze data from conference activities that pertain to the impact on prevention. Adequately assess increased knowledge, attitudes, and behaviors of the target audience.

9. Analyze data from conference activities that pertain to the impact of prevention. Adequately assess increased knowledge, attitudes, and behaviors of the target audience.

10. ATSDR grantees must collaborate with ATSDR staff in reporting and disseminating results and relevant prevention education and training information to appropriate Federal, State, and local agencies, and the general public.

E. Application Content

Note: HIV applicants go to Appendix 4.

Letter of Intent (LOI)

Interested applicants are required to submit an original and two copies of a two to three-page in-depth typewritten Letter of Intent (LOI). Upon review of the LOI's, CDC or ATSDR will extend written invitations to perspective applicants to submit applications. CDC or ATSDR will accept applications by invitation only. Availability of funds may limit the number of applicants, regardless of merit, that receive an invitation to submit applications. The LOI should specifically describe the following required information:

1. Title of the proposed conference—include the term ''conference,'' ''symposium,'' ''workshop,'' or similar designation;

2. Location of conference—city, state, and physical facilities required for the conduct of the meeting;

3. Expected registration—the intended audience, approximate number and profession of persons expected to attend;

4. Date(s) of conference—inclusive dates of conference (LOIs without date

of conference will be considered non-responsive to this program announcement and returned to the applicant without review);

5. Summary of conference format, projected agenda (including list of principal areas or topics to be addressed), including speakers or facilitator. In addition, information should be provided about all other national, regional, and local conferences held on the same or similar subject during the last three years; and

6. Justification of the conference, including the problems it intends to clarify and the developments it may stimulate.

Also include the name of the organization, primary contact person's name, mailing address, telephone number, and if available, fax number and e-mail address. The LOI must include the estimated total cost of the conference and the percentage of the total cost (which must be less than 100%) being requested from CDC or ATSDR. Requests for 100 percent funding will be considered non-responsive to this program announcement and will be returned to the applicant without review. Current recipients of CDC and ATSDR funding must provide the award number and title of their funded programs. No Appendixes, booklets, or other documents accompanying the LOI will be considered. An invitation to submit an application will be made on the basis of the proposed conference's relationship, as outlined in the LOI, to the CDC or ATSDR funding priorities and availability of funds. LOIs should be provided by over night mail service, or U.S. postal service.

THE THREE PAGE LIMITATION (INCLUSIVE OF LETTERHEAD AND SIGNATURES) MUST BE OBSERVED OR THE LETTER OF INTENT WILL BE RETURNED WITHOUT REVIEW.

Application

(HIV applicants go to Appendix 4 for HIV application content.)

A letter of intent (LOI) is required for this Program Announcement. Applicants may apply to CDC or ATSDR for conference support only after their LOI has been reviewed by CDC and ATSDR and a written invitation, including an application form, has been received by the prospective applicant. An invitation to submit an application does not constitute a commitment on the part of CDC or ATSDR to fund the application.

In addition to the following required information, use the information in the Program Requirements and Evaluation Criteria sections to develop the application content.

1. A project summary cover sheet that includes:
   (a) Name of organization.
   (b) Name of conference.
   (c) Location of conference.
   (d) Date(s) of conference.
   (e) Intended audience and number.
   (f) Dollar amount requested.
   (g) Total conference budget amount.

2. A brief background of the organization—include the organizational history, purpose, and previous experience related to the proposed conference topic.

3. A clear statement of the need for and purpose of the conference. This statement should also describe any problems the conference will address or seek to solve, and the action items or resolutions it may stimulate.

4. An elaboration on the conference objectives and target audience. A list should be included of the principal areas or topics to be addressed. A proposed or final agenda must be included.

5. A clear description of the evaluation plan and how it will assess the accomplishments of the conference objectives. A sample of the evaluation instrument that will be used must be included.

6. A step-by-step schedule and detailed operation plan of major conference planning activities necessary to attain specified objectives.

7. Biographical sketches are required for the individuals responsible for planning and implementing the conference. Experience and training related to conference planning and implementation as it relates to the proposed topic should be noted.

8. Letters of endorsement or support—Letters of endorsement or support for the sponsoring organization and its capability to perform the proposed conference activity.

9. Budget plan and justification—A clearly justified budget narrative that is consistent with the purpose, objectives, and operation plan of the conference. This will consist of a budget that includes the share requested from CDC or ATSDR as well as those funds from other sources, including organizations, institutions, conference income and/or registration fees.

The narrative should be no more than 12 double-spaced pages, printed on one side, with one-inch margins, and 12-point font. Pages must be clearly numbered, and a complete index to the application and its appendices must be included. The original and two required copies of the application must be submitted UNSTAPLED AND UNBOUND. Materials which should be part of the basic plan should not be in the appendices.

F. Submission and Deadline

Letter of Intent (LOI), Letter of Intent Due Dates: Cycle A: October 1, 1999 For conferences May 1, 2000–April 30,2001

Cycle B: January 3, 2000, For Conferences August 1, 2000–July 31, 2001

Cycle C: April 3, 2000, For Conferences November 1, 2000–September 30, 2001

On or before October 1, 1999, January 3, 2000, or April 3, 2000, applicant must submit an original and two (2) copies of the LOI to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Application

Applicant invited to apply should submit the original and two copies of PHS application form 5161–1, revised 7/92 (OMB Number 0937–0189). Forms are in the application kit with the letter inviting submission for one of these three dates.

Application due dates	Earliest possible award dates
CYCLE A: December 13, 1999.	April 1, 2000
CYCLE B: March 13, 2000.	July 1, 2000
CYCLE C: June 16, 2000.	September 30, 2000

Applications with a conference date that occurs within sixty days of date of submission of application will be considered non-responsive.

Submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Deadline: Letters of Intent and Applications shall be considered as meeting the deadline if they are either:

(1) Received on or before the date, or

(2) Postmarked on or before the deadline date and received in time for orderly processing. (Applicants must request a legibly dated U.S. Postal Service Postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

(3) Late Applications: Applications, which do not meet the criteria in (1) or (2) above, are considered late

applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

(HIV applicants go to Appendix 5 for Evaluation criteria)

Letter of Intent

A conference is a symposium, seminar, workshop, or any other organized and formal meeting lasting portions of 1 or more days, where persons assemble to exchange information and views or explore or clarify a defined subject, problem, or area of knowledge, whether or not a published report results from such meeting. The conference should support CDC or ATSDR's public health principles in furtherance of CDC's mission or ATSDR's mission.

Application

CDC and ATSDR Public Health Conference Support Grant Program applications are each objectively reviewed utilizing the following evaluation criteria:

Section 1.a., is ATSDR specific

Section 1.b., is CDC specific

Section 1.c., and all other sections in these criteria are applicable to both CDC and ATSDR,

except for HIV Prevention (see Appendix 5)

1. PROPOSED PROGRAM AND TECHNICAL APPROACH (25 points)

a. The public health significance of the proposed conference including the degree to which the conference can be expected to influence the prevention of exposure and adverse human health effects and diminished quality of life associated with exposure to hazardous substances from waste sites, unplanned releases and other sources of pollution present in the environment. (Applicable to ATSDR applications only).

b. The applicant's description of the proposed conference as it relates to specific non-Federal conferences in the areas of health promotion and disease prevention information/education programs (except mental health, and substance abuse), including the public health need of the proposed conference and the degree to which the conference can be expected to influence public health practices. Evaluation will be based also on the extent of the applicant's collaboration with other organizations serving the intended audience. (Applicable to all CDC applications except ATSDR and HIV.)

c. The applicant's description of conference objectives in terms of quality, specificity, and the feasibility of the conference based on the operational plan.

2. APPLICANT'S CAPABILITY (10 points)

Adequacy of applicants' resources (additional sources of funding, organization's strengths, staff time, proposed physical facilities, etc.) available for conducting conference activities.

3. THE QUALIFICATION OF PROGRAM PERSONNEL (20 points)

Evaluation will be based on the extent to which the application has described:

a. The qualifications, experience, and commitment of the principal staff person, and his/her ability to devote adequate time and effort to provide effective leadership.

b. The competence of associate staff persons, discussion leaders, speakers, and presenters to accomplish conference objectives.

c. The degree to which the applicant demonstrates the knowledge of nationwide and educational efforts currently underway which may affect, and be affected by, the proposed conference.

4. CONFERENCE OBJECTIVES (25 points)

a. The overall quality, reasonableness, feasibility, and logic of the designed conference objectives, including the overall work plan and timetable for accomplishment.

b. The likelihood of accomplishing conference objectives as they relate to disease prevention and health promotion goals, and the feasibility of the project in terms of the operational plan.

5. EVALUATION METHODS (20 points)

Evaluation instrument(s) for the conference should adequately assess increased knowledge, attitudes, and behaviors of the target audience.

6. BUDGET JUSTIFICATION AND ADEQUACY OF FACILITIES (not scored)

The proposed budget will be evaluated on the basis of its reasonableness; concise and clear justification; and consistency with the intended use of grant funds. The application will also be reviewed as to the adequacy of existing or proposed facilities and resources for conducting conference activities.

H. Other Requirements

Technical Reporting Requirements

Provide the Grants Management Office with original plus two copies of:

1. A Performance Report, or in lieu of a performance report, proceedings of the conference, no more than 90 days after the end of the budget/project period.

2. A Financial Status Report, no more than 90 days after the end of the budget/project period.

Send all reports to:

Julia L. Valentine, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Koger Center, Colgate Bldg., 2920 Brandywine Road, MS E–15, Atlanta, Georgia 30341–3724.

The following additional requirements are applicable to this program. For a complete description of each, see Appendix I.

AR–5 HIV Program Review Panel Requirements.

AR–7 Executive Order 12372 Review.

AR–8 Public Health System Reporting Requirements.

AR–9 Paperwork Reduction Act Requirements.

AR–10 Smoke-Free Workplace Requirements.

AR–11 Healthy People 2000.

AR–12 Lobbying Restrictions.

AR–15 Proof of Non-Profit Status.

AR–20 Conference Support.

I. Authority and Catalog of Federal Domestic Assistance Number

The CDC program is authorized under the Public Health Service Act, section 301 (42 U.S.C. 241, as amended). The Catalog of Federal Domestic Assistance number is 93.283.

The HIV Prevention program is authorized under the Public Health Service Act (42 U.S.C. 317 (k) (2) of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.941.

The ATSDR program is authorized under sections 104(i) (14) and (15) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), (42 U.S.C. 9604(i) (14) and (15)). The Catalog of Federal Domestic Assistance number is 93.161.

J. Where To Obtain Additional Information

To receive additional written information, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest. See also the CDC home page on the Internet: http://www.cdc.gov/od/pgo/forminfo.htm.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Julia L. Valentine, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease

Control and Prevention (CDC), Koger Center, Colgate Bldg., 2920 Brandywine Road, MS E–15, Atlanta, Georgia 30341–3724, Telephone (770) 488–6871, Email address: jxvl@cdc.gov.

For program technical assistance, contact: C.E. Criss Crissman, Resource Analysis Specialist, Office of the Director/Extramural Services Activity, Public Health Practice Program Office (PHPPO), Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, MS K–38, Atlanta, Georgia 30341–3714, Telephone (770) 488–2513, Email address cec1@cdc.gov.

Dated: August 13, 1999.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–21505 Filed 8–18–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Research Studies to Characterize the Clinical Relevance of HIV Superinfection

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Research Studies to Characterize the Clinical Relevance of HIV Superinfection, Program Announcement #99105.

Times and Dates: 9 a.m.–9:30 a.m., August 27, 1999 (Open) 9:30 a.m.–4:30 p.m., August 27, 1999 (Closed).

Place: Professional and Scientific Associates, 2635 Century Parkway, Suite 990, Atlanta, GA. 30345. Telephone 404/633–6477.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement #99105. Due to administrative delays this notice is published less than 15 days prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Nancy Pearcey, Prevention Support Office, National Center for HIV, STD, and TB Prevention, CDC, Corporate Square Office Park, 11 Corporate Square Boulevard, M/S E07, Atlanta, Georgia 30329, telephone 404/639–8025, e-mail nxp1@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 12, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–21503 Filed 8–16–99; 12:19 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Social and Environmental Interventions to Reduce HIV Incidence

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Social and Environmental Interventions to Reduce HIV Incidence, Program Announcement #99106.

Times and Dates: 8:30 a.m.–9 a.m., August 27, 1999 (Open) 9 a.m.–4:30 p.m., August 27, 1999 (Closed).

Place: CDC, Executive Park Building 16, Conference Room B, Executive Park Drive, Atlanta, GA. 30329.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement #99106. Due to administrative delays this notice is published less than 15 days prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Nancy Pearcey, Prevention Support Office, National Center for HIV, STD, and TB Prevention, CDC, Corporate Square Office Park, 11 Corporate Square Boulevard, M/S E07, Atlanta, Georgia 30329, telephone 404/639–8025, e-mail nxp1@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 12, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–21504 Filed 8–16–99; 12:19 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Grant To American Public Human Services Association

AGENCY: Office of Family Assistance, ACF, DHHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that an award is being made to the American Public Human Services Association (APHSA) of Washington, DC in the amount of $15,000 for support to their Executive Leadership Institute. After the appropriate reviews, it has been determined that this proposal qualifies as a sole source award. The Executive Leadership Institute of APHSA is designed by and for State Human Service Administrators and offers various educational activities that will enhance the skills and leadership capacity of State Human Service Administrators and other high-level policy makers involved in implementation of State TANF Programs.

The American Public Human Services Association is a very unique organization in the Welfare Reform community. The mission of APHSA is to develop, promote, and implement pubic human service policies that improve the health and well being of families, children, and adults. APHSA educates members of Congress, the media, and the broader public on what is happening in the States concerning

welfare, child welfare, healthcare reform, and other issues that directly impact the TANF program. The Executive Leadership Institute focuses its efforts on the top State Human Service Executive and Senior Managers and other high level policy makers. By partnering with APHSA on this project, the Administration for Children and Families will further its goal in Welfare Reform by enhancing the skills and leadership capacity of the Human Service Administrators and other high level policy makers involved in implementing TANF programs. The period of this funding will extend through May 31, 2000.

FOR FURTHER INFORMATION CONTACT: Paul Maiers, Office of Family Assistance, Administration for Children and Families, 370 L'Enfant Promenade, SW, Washington, DC 20447, Telephone: 202–401–5438.

Dated: August 10, 1999.

Alvin C. Collins,

Director, Office of Family Assistance.

[FR Doc. 99–21476 Filed 8–18–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–72]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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: Extension of a currently approved collection.

Title of Information Collection: Information Collection Requirements in 42 CFR 473.18, 473.34, 473.36, and 473.42, PRO Reconsiderations and Appeals.

Form No.: HCFA–R–72 (OMB# 0938–0443).

Use: These requirements contain procedures for PROs to use in reconsideration of initial determinations. The information requirements contained in these regulations are on PROs to provide information to parties requesting a reconsideration. These parties will use the information as guidelines for appeal rights in instances where issues are still in dispute.

Frequency: On occasion.

Affected Public: Individuals or Households, Business or other for-profit.

Number of Respondents: 53.

Total Annual Responses: 15,670.

Total Annual Hours: 3,578.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, 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, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 10, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–21554 Filed 8–18–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–718–721]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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: Revision of a currently approved collection.

Title of Information Collection: Business Proposal Formats for Utilization and Quality Control Peer Review Organizations (PROs).

Form No.: HCFA–718–721 (OMB# 0938–0579).

Use: The information collected on these forms by current Peer Review Organizations (PROs) and other bidders will provide HCFA with the necessary information to evaluate their contract proposals. This information will satisfy the need for meaningful, consistent, and verifiable data. With this data, HCFA will be able to compare the costs reported by the PROs on the cost reports to the proposed costs noted on the business proposal forms.

Frequency: Other: Tri-Annually.

Affected Public: Business or other for-profit, and Not-for-profit institutions.

Number of Respondents: 20.

Total Annual Responses: 20.

Total Annual Hours: 535.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your

request, including your address, phone number, OMB number, and HCFA document identifier, 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, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 10, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–21556 Filed 8–19–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–838]

Agency Information Collection Activities: Submission For OMB Review; 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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. 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.

Type of Information Collection Request: Extension of a currently approved collection.

Title of Information Collection: Medicare Credit Balance Reporting Requirements and Supporting Regulations in 42 CFR 413.20, 405.371 and 405.378.

Form No.: HCFA–838 (OMB# 0938–0600).

Use: Section 1866(a)(1)(C) of the Social Security Act requires health care providers participating in the Medicare program, to make adequate provisions to refund any monies incorrectly paid by Medicare. This collection of credit balance information is needed to ensure that the millions of dollars in improper program payments are collected. Approximately 47,600 health care providers will be required to submit a quarterly credit balance report that identifies the amount of improper payments they receive that are due to Medicare. The intermediaries will monitor the reports to ensure these funds are collected.

Frequency: Quarterly.

Affected Public: Not-for-profit institutions, and Business or other for-profit.

Number of Respondents: 47,600.

Total Annual Responses: 190,400.

Total Annual Hours: 1,142,400.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or 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 designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 5, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–21555 Filed 8–18–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Call for Public Comment: Changing the Conversation—A National Plan to Improve Substance Abuse Treatment

AGENCY: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, DHHS.

ACTION: Request for public comment on five issues (domains) of concern to the substance abuse treatment field when assessing substance abuse treatment.

SUMMARY: This notice announces that the Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) is formally inviting public comment on five issues (domains) that are of concern to the substance abuse treatment field and require development and exploration. Via several mechanisms, including public hearings, CSAT intends that findings from the exploration of individual domains will ultimately be synthesized into a coherent national strategy to guide substance abuse treatment program and policy development for the future. Individuals and organizations are encouraged to comment in one of several ways: (1) in writing, by submission through the U.S. Mail or courier service; (2) via the National Treatment Plan web site (http://www.NaTxPlan.org); or (3) in person at one of the remaining four public hearings scheduled at locations across the country. The final cutoff date for comments is December 1, 1999. This notice discusses the public hearings at which interested individuals/organizations may testify regarding the five substance abuse treatment domains discussed below.

DATES/LOCATIONS: In addition to the public hearing held on July 8 in Hartford, Connecticut, CSAT plans to conduct four more public hearings in 1999—September 16 in Chicago, Illinois; October in Portland, Oregon, and Washington, DC; and November in Tampa/St. Petersburg, Florida. The next hearing will be held at Loyola University, Water Tower Campus, Marquette Center (2nd Floor), Georgetown Room, Corner of Rush and Pearson Streets, Chicago, Illinois 60611, on September 16, 1999, between the hours of 8:30 a.m. and 5:00 p.m. Specific details regarding subsequent hearings will be published in the **Federal Register** approximately one month prior to each hearing.

Requests to testify at the Chicago, Illinois, public hearing must be submitted to the addressee indicated below by September 9, 1999. Seating is limited. In the event that interpretive services for the hearing-impaired are required, please indicate these special needs to the addressee.

FOR FURTHER INFORMATION CONTACT: Requests for additional information regarding the hearing and/or testimonies, as well as requests to testify must be addressed to: Peggy Cockrill,

[Tele: (301) 443–7024; e-mail: pcockril@samhsa.gov; Fax: (301) 480–6077], Center for Substance Abuse Treatment, SAMHSA, Rockwall II Building, Suite 618, 5600 Fishers Lane, Rockville, Maryland 20857.

Written comments (without a request to personally testify) will also be accepted by the above addressee. Written testimonies are limited to five (5) typed pages using 1.5 line spacing and 12 point font.

SUPPLEMENTARY INFORMATION:

Background

Building on recent advances and studies, CSAT has initiated plans to focus on how to apply its extensive knowledge to the practical objective of improving treatment outcomes. The plans include synthesizing current knowledge and recommendations about treatment, service systems, application of best practices, diffusion methods, and organization and financing of substance abuse treatment services. Federal Government and outside experts, as well as the interested public, will explore the current state of the knowledge, resources, needs, and service and organizational capacity. The objective is the culling of priorities for action by the government and by others in the substance abuse treatment field. As noted above, CSAT is inviting the public to comment on five domains as part of the initial step of the plan. The domains, as well as some initial questions for exploration, include:

(1) Closing the Treatment Gap: Where are the gaps? How big are they for different populations? For different types of settings and treatment modalities? How big are gaps in other related systems of care, e.g., welfare, child welfare, housing? What are the policy, organization, and financing issues that must be addressed in the private and public systems, including Medicaid and Medicare, to close the treatment gap?

(2) Reducing Stigma and Changing Attitudes: What are the nature, causes and consequences of addiction stigma? What can CSAT, the treatment field, consumers and families do to address stigma related to addiction, substance abuse treatment and individuals with substance abuse disorders? How do other stigmas impact/compound the stigma of addiction?

(3) Improving and Strengthening Treatment Systems: What are the clinical and organizational challenges facing treatment organizations in the public and private sectors? What can CSAT, the treatment field, consumers and families do to improve and strengthen treatment organizations so that they can adapt to the new imperatives of the changing treatment system, and to improve the relationship between the general health care system and the specialty substance abuse treatment system? What should be done at the State, county and/or local levels to improve and strengthen substance abuse treatment?

(4) Connecting Services and Research: What are the best methods by which CSAT, the treatment field, consumers and families can foster and support evaluation of proven research findings in community-based settings and identification and adoption of best practices?

(5) Addressing Workforce Issues: What are the issues facing clinicians treating addictions? What can CSAT, the treatment field, consumers and families, and professional associations do to foster training, appropriate credentialing, and licensure in all settings in which treatment occurs, and to support treatment organizations in developing appropriate policies for clinical training?

Hearing Format

The hearings will be divided into five segments (i.e., the five domains described above) of approximately 45–60 minutes each. Each individual/organization participant will be limited to three (3) minutes of oral testimony and five (5) pages of typed testimony per domain. All oral testimonies must be accompanied by a written testimony of no more than five (5) typed pages using 1.5 line spacing and 12 point font. Five copies of written testimonies may either be submitted before the hearing to the addressee listed above or to the registrar at the hearing. As the hearing schedule allows, unscheduled testimonies will be accommodated. All testimonies (recorded and written) will become a part of the public domain.

Dated: August 12, 1999.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 99–21475 Filed 8–18–99; 8:45 am]

BILLING CODE 4162–20–U

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*):

PRT–016026

Applicant: John T. Hughes, Muskegon, MI

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

PRT–016089

Applicant: Morgan Wynne, Anchorage, AK

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

PRT–016149

Applicant: Wilson Seay Stout, Dallas, TX

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

PRT–016158

Applicant: International Animal Exchange, Ferndale, MI

The applicant requests a permit to export 1.0 captive born black leopard (*Panthera pardus*) to Baijing Badaling Wild Animal World, Beijing, China, for the purposes of public display, education and captive breeding.

Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

The following applicants have applied for a permit to conduct certain activities with marine mammals. The application was submitted to satisfy requirements of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*), and the regulations governing marine mammals (50 CFR 18).

PRT–016090

Applicant: Harry Koch, Heath, TX

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport-hunted from the Lancaster Sound polar bear population, Northwest Territories, Canada for personal use.

Documents and other information submitted with these applications are

available for review, *subject to the requirements of the Privacy Act and Freedom of Information Act,* by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203. Phone: (703/358–2104); FAX: (703/358–2281).

Dated: August 13, 1999.

Pam Hall,

Acting Chief, Branch of Permits, Office of Management Authority.

[FR Doc. 99–21473 Filed 8–18–99; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Migratory Bird Permits; Notice of Intent To Prepare an Environmental Impact Statement on Resident Canada Goose Management

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent.

SUMMARY: The U.S. Fish and Wildlife Service (Service or we) is issuing this notice to advise the public that we are initiating efforts to prepare an Environmental Impact Statement (EIS) for resident Canada goose management under the authority of the Migratory Bird Treaty Act. The EIS will consider a range of management alternatives for addressing expanding populations of locally-breeding Canada geese that are increasingly posing threats to health and human safety and injuring personal and public property. This notice describes possible alternatives, invites public participation in the scoping process for preparing the EIS, and identifies the Service official to whom you may direct questions and comments. While we have yet to determine potential sites of public scoping meetings, we will publish a notice of any such public meetings with the locations, dates, and times in the **Federal Register**.

DATES: You must submit written comments regarding EIS scoping by October 18, 1999, to the address below.

ADDRESSES: You should send written comments to the Chief, Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, ms 634—ARLSQ, 1849 C Street NW., Washington, D.C. 20240. All comments received, including names and addresses, will become part of the public record. You may inspect comments during normal business hours in room 634—Arlington Square Building, 4401 N. Fairfax Drive, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: Jonathan Andrew, Chief, or Ron W. Kokel, Office of Migratory Bird Management, U.S. Fish and Wildlife Service, (703) 358–1714.

SUPPLEMENTARY INFORMATION:

Background

Numbers of Canada geese that nest and reside predominantly within the conterminous United States have increased exponentially in recent years. These geese are usually referred to as ''resident'' Canada geese. Recent surveys in the Atlantic, Mississippi, and Central Flyways suggest that the resident breeding population now exceeds 1 million individuals in both the Atlantic and Mississippi Flyways is increasing dramatically. Because resident Canada geese live in temperate climates with relatively stable breeding habitat conditions and low numbers of predators, tolerate human and other disturbances, have a relative abundance of preferred habitat provided by current urban/suburban landscaping techniques, and fly relatively short distances to winter compared with other Canada goose populations, they exhibit a consistently high annual production and survival. Given these characteristics, the absence of waterfowl hunting in many of these areas, and free food handouts by some people, these urban/suburban resident Canada goose populations are increasingly coming into conflict with human activities in many parts of the country.

Conflicts between geese and people affect or damage several types of resources, including property, human health and safety, agriculture, and natural resources. Common problem areas include public parks, airports, public beaches and swimming facilities, water-treatment reservoirs, corporate business areas, golf courses, schools, college campuses, private lawns, amusement parks, cemeteries, hospitals, residential subdivisions, and along or between highways.

Property damage usually involves landscaping and walkways, most commonly on golf courses and waterfront property. In parks and other open areas near water, large goose flocks create local problems with their abundant droppings and feather litter (Conover and Chasko, 1985). Surveys have found that while most landowners like seeing some geese on their property, eventually, increasing numbers of geese and the associated accumulation of goose droppings on lawns cause many landowners to view geese as a nuisance and thus reduce both the aesthetic value and recreational use of these areas (Conover and Chasko, 1985).

Negative impacts on human health and safety occur in several ways. At airports, large numbers of geese can create a very serious threat to aviation. Resident Canada geese have been involved in a large number of aircraft strikes resulting in dangerous landing/take-off conditions and costly repairs. As a result, many airports have active goose control programs. Excessive goose droppings are a disease concern for many people. Public beaches in several States have been closed due to excessive fecal coliform levels that in some cases have been traced back to geese and other waterfowl. Additionally, during nesting and brood rearing, aggressive geese have bitten and chased people.

Agricultural and natural resource impacts include losses to grain crops, overgrazing of pastures, and degrading water quality. Goose droppings in heavy concentrations can overfertilize lawns and degrade water quality resulting in eutrophication of lakes with excessive algae growth (Manny *et al.*, 1994). Overall, complaints related to personal and public property damage, agricultural damage and other public conflicts are increasing as resident Canada goose populations increase.

Until recently, we attempted to address this growing problem through existing annual hunting season frameworks and the issuance of control permits on a case-by-case basis. While this approach provided relief in some areas, it did not completely address the problem. On June 17, we published a final rule in the **Federal Register** (64 FR 32766) establishing a new special Canada goose permit. The new permits are specifically for the management and control of resident Canada geese. We will issue permits to State conservation or wildlife management agencies on a State-specific basis, so States and their designated agents can initiate resident goose damage management and control injury problems within the conditions and restrictions of the permit program. The permits, while restricted to the period between March 11 and August 31, increase the use and availability of control measures, decrease the number of injurious resident Canada geese in localized areas, have little impact on hunting or other recreation dependent on the availability of resident Canada geese, and allow injury/damage problems to be dealt with on the State and local level, thereby resulting in more responsive and timely control activities. The new special permits

further result in biologically sound and more cost-effective and efficient resident Canada goose damage management. Overall, the new permit will provide some additional management flexibility needed to address this serious problem and at the same time simplify the procedures needed to administer this program. In the short term, we believe this permit will satisfy the need for an efficient/cost-effective program while allowing us to maintain management control.

In the long-term, however, we realize that more management flexibility will likely be necessary. Because of the unique locations where large numbers of these geese nest, feed, and reside, we continue to believe that new and innovative approaches and strategies for dealing with bird/human conflicts will be needed. We have recently begun the initial work, with the full assistance and cooperation of the Flyway Councils and the Wildlife Services program of the Animal and Plant Health Inspection Service (APHIS/WS), to develop a long-term strategy to integrate our management of these birds into a larger Flyway management plan system. In order to properly examine alternative strategies to control and manage resident Canada geese that either pose a threat to health and human safety or cause damage to personal and public property, the preparation of an EIS is necessary.

Resident Canada Goose Populations

Canada geese, like other geese, are long-lived birds with relatively low reproduction rates and high survival rates. However, of all the Canada goose subspecies, the subspecies comprising most resident geese have a higher reproductive and adult survival rate. While arctic and subarctic Canada goose survival and reproduction are greatly influenced by weather conditions, resident geese live in more temperate climates with relatively stable breeding habitat conditions and low numbers of predators. Additionally, nesting resident geese are very tolerant of human disturbance and willing to nest in close proximity to other geese (Gosser and Conover, 1999; Zenner and LaGrange, 1998). Urban and suburban landscaping in the conterminous United States offers resident geese a relative abundance of preferred habitat (park-like open areas with short grass adjacent to small bodies of water). Also, resident geese fly relatively short distances to winter compared with other Canada goose populations. All of these factors result in consistently high annual reproduction and survival for the resident Canada goose population.

In recent years, the numbers of Canada geese that nest predominantly within the conterminous United States have increased tremendously. Recent surveys in the Atlantic, Mississippi, and Central Flyways (Wood *et al.*, 1994; Kelley *et al.*, 1998; Nelson and Oetting, 1998; Sheaffer and Malecki, 1998; Wilkins and Cooch, 1999) suggest that the resident breeding population now exceeds 1 million individuals in both the Atlantic (17 States) and Mississippi (14 States) Flyways. Available information shows that in the Atlantic Flyway, the resident population has increased an average of 14 percent per year since 1989. In the Mississippi Flyway, the resident population of Canada geese has increased at a rate of about 6 percent per year during the last 10 years. In the Central and Pacific Flyways, populations of resident Canada geese have similarly increased over the last few years. For example, in the Puget Sound area of Washington, a 10-year trend shows an increase from 3,110 geese in 1988 to 13,512 geese in 1997, an increase of 434%. We remain concerned about the rapid growth rate exhibited by these already large populations.

Current Management Actions

To date, we have tried to address injurious resident Canada goose problems through existing hunting seasons, the creation of new special Canada goose seasons designed to target resident populations, the issuance of depredation permits allowing specific control activities, and the creation of a new special Canada goose permit.

(1) Special Hunting Seasons

Special Canada goose seasons are hunting seasons specifically designed to target resident populations through either time or area restrictions. We first initiated special seasons targeting resident Canada geese in 1977 in the Mississippi Flyway with an experimental late season in Michigan. The original intent of these special seasons was to provide additional harvest opportunities on resident Canada geese while minimizing impacts to migrant geese. Initially, we considered all such seasons experimental, pending a thorough review of the data gathered by the participating State. We presently offer special seasons targeting resident Canada geese in all four Flyways, with 31 States participating. They are most popular among States when regular Canada goose seasons are restricted to protect migrant populations of Canada geese.

Harvest of Canada geese during these special seasons has increased substantially over the last 10 years. In the Atlantic Flyway, 16 of 17 States hold special Canada goose seasons, with harvest rising from about 2,300 in 1988 to over 272,000 in 1998. In the Mississippi Flyway, 11 of 14 States hold special Canada goose seasons, and harvest has increased from slightly more than 1,000 in 1981 to over 275,000 in 1998. Both Minnesota and Michigan currently harvest in excess of 70,000 locally-breeding Canada geese per year. While the harvest opportunities are not as significant in the Central and Pacific Flyways, as areas and seasons have expanded, harvest has increased from approximately 1,300 in 1989 to almost 40,000 in 1998. Putting these harvest numbers in perspective, Martin and Padding (1999) estimated that hunters harvested a total of 2,038,700 Canada geese last year in the U.S. Thus, conservatively, resident Canada geese now comprise roughly 30% of the total Canada goose harvest in the U.S. (587,000 of 2,038,700). However, despite these dramatic increases in harvest over the last 10 years, from less than 24,000 in 1988 to over 587,000 last year (a 24-fold increase), populations continue to increase in all Flyways.

Creation of these special harvest opportunities has helped to limit the problems and conflicts between geese and people in some areas. However, many resident Canada geese remain in urban and suburban areas throughout the fall and winter where these areas afford them almost complete protection from sport harvest. Thus, while the creation of these special hunting seasons is our first management tool of choice for dealing with most resident Canada goose conflicts, we realized that harvest management will never completely address this growing problem and permits to conduct otherwise prohibited control activities will continue to be necessary to balance human needs with expanding resident Canada goose populations.

(2) Depredation Permits

Complex Federal and State responsibilities are involved with all migratory bird control activities, including the control of resident Canada geese. All State and private control activities require a Federal migratory bird permit. These permits are issued in coordination with APHIS/WS. APHIS/WS is the Federal Agency with lead responsibility for dealing with wildlife damage complaints. In some instances, APHIS/WS may do the goose damage management work directly or they may

serve as agents working under authority of private and/or State permits.

However, APHIS/WS has limited personnel and resources to respond to requests for assistance. Likewise, as the number of complaints and conflicts continue to increase, the public will place greater demand on us and the States to assist in goose public-health and damage-management programs. This increased need for assistance places greater demand on the current permit-issuance system. Unfortunately, administrative procedures involved in the issuance of permits many times cause a lag time of several weeks between our receipt of a permit request, our evaluation and decision on issuing the permit, and the ultimate issuance of a site-specific permit authorizing a control action. In the interim, even small numbers of geese can cause significant damage to personal property and result in economic, recreational, and aesthetic losses. Thus, with the increase in complaints, the case-by-case permit issuance system can be time-consuming, cumbersome and inefficient for us and the States.

A brief summary of the complaints/requests for control permits placed with APHIS/WS indicates the increasing number of public conflicts. In 1997, APHIS/WS received 3,295 complaints of injurious Canada goose activity (APHIS/WS, 1998). In response to those complaints, APHIS/WS recommended we issue 354 permits. The vast majority of these complaints concerned agricultural, human health and safety, and property issues and came primarily from the Northeastern/New England area (50%) and the Upper Midwest/Great Lakes area (29%). Comparing these figures with previous years' data shows a steady increase in complaints since 1991. In 1991 APHIS/WS received 1,698 complaints of injurious Canada goose activity (APHIS/WS, 1992). In response to those complaints, APHIS/WS recommended we issue 92 permits.

Thus, our permit issuance has increased tremendously in recent years. For example, Region 5 (the Northeastern/New England area) issued 26 site-specific permits to kill resident Canada geese and 54 permits to addle eggs in 1994. Two years later in 1996, Region 5 issued 70 site-specific permits to kill resident Canada geese, 1 permit to relocate geese, and 151 permits to addle eggs. In addition, the Region issued Statewide permits to relocate birds and addle eggs to agencies in certain States. Over 3 years, these permits resulted in the relocation of over 2,600 geese, the addling of eggs in over 2,300 nests, and the take of over 1,000 birds.

In Region 3, the Upper Midwest/Great Lakes area, in 1994, the Region issued 149 permits authorizing resident Canada goose control activities, including trapping and relocation, destruction of nests/eggs, and take of adults. In 1998, Region 3 issued 225 permits authorizing resident Canada goose control activities. In total over the last 5 years, Region 3 permit holders, including APHIS/WS, airports, and state wildlife agencies, reported taking in excess of 27,000 eggs and 6,800 geese, and trapped and relocated over 70,000 resident Canada geese (complete reports through 1997, partial reports for 1998). States in which control activities were conducted included Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin.

Since 1995, Region 3 has also issued permits to the Michigan Department of Natural Resources and the Minnesota Department of Natural Resources authorizing the capture and processing of resident Canada geese as food for local food-shelf programs. Minnesota's permit was a part of the their Urban Goose Management Program for the Minneapolis-St. Paul Metropolitan Area (initiated in 1982). In 1995, the first year under these permits, Michigan and Minnesota were authorized to take up to 2,000 and 325 geese, respectively. Michigan reported taking 24 birds with Minnesota taking its full allotment of 325 birds. Since then, Minnesota has been authorized to annually take up to 2,500 resident Canada geese for its food-shelf program. In the three years under the program since 1995, Minnesota has reported taking 5,399 birds. Likewise, Michigan was also issued permits for 1996–1998 authorizing the take up to 1,000 resident Canada geese for its food-shelf programs. Michigan subsequently reported taking 490 birds in 1996 and 952 birds in 1997, before vacating their 1998 permit.

In Region 1, the Pacific Northwest/West Coast area, we have primarily limited permits for the control of resident Canada geese to the addling of eggs. In 1995, the Region issued permits authorizing the take of 900 eggs in the Puget Sound Area of Washington. In 1996, this number was increased to 2,000 eggs and 200 adult birds. APHIS/WS subsequently reported taking 911 and 1,570 eggs in 1995 and 1996, respectively, and 6 geese in 1996.

(3) Special Canada goose permits

On June 17, we published in the **Federal Register** (64 FR 32766) a final rule establishing a new special Canada goose permit. Designed specifically for the management and control of resident Canada geese, the new permits are only available to State conservation or wildlife management agencies on a State-specific basis. Under the permits, States and their designated agents can initiate resident goose damage management and control injury problems within the conditions and restrictions of the permit program. The permits, while restricted to the period between March 11 and August 31, increase the use and availability of control measures, decrease the number of injurious resident Canada geese in localized areas, have little impact on hunting or other recreation dependent on the availability of resident Canada geese, and allow injury/damage problems to be dealt with on the State and local level, thereby resulting in more responsive and timely control activities. State applications for the special permits require several detailed statements regarding the size of the resident Canada goose breeding population in the State and the number of resident Canada geese, including eggs and nests, to be taken. In addition, the State must show that such damage-control actions will either provide for human health and safety or protect personal property, or compelling justification that the permit is needed to allow resolution of other conflicts between people and resident Canada geese. Briefly, some of the more pertinent restrictions in the new permits are:

1. State wildlife agencies (States) may take injurious resident Canada geese as a management tool but should utilize non-lethal management tools to the extent they consider appropriate in an effort to minimize lethal take.

2. Control activities should not adversely affect other migratory birds or any species designated under the Endangered Species Act as threatened or endangered.

3. States may conduct control activities March 11 through August 31 and should make a concerted effort to limit the take of adult birds to June, July, and August in order to minimize the potential impact on other migrant populations.

4. States must conduct control activities clearly as such (*e.g.*, they cannot be set up to provide a hunting opportunity).

5. States must properly dispose of or utilize Canada geese killed in control programs. States may donate Canada geese killed under these permits to public museums or public scientific and educational institutions for exhibition, scientific, or educational purposes, or charities for human consumption. States may also bury or incinerate geese. States may not allow for Canada geese taken under these permits, nor their plumage, to be sold, offered for sale, bartered, or shipped for purpose of sale or barter.

6. States may use their own discretion for methods of take but utilized methods should

be consistent with accepted wildlife-damage management programs.

7. States may designate agents who must operate under the conditions of the State's permit.

8. States must keep records of all activities, including those of designated agents, carried out under the special permits. We will require an annual report detailing activities conducted under a permit.

9. We will annually review States' reports and will periodically assess the overall impact of this program to ensure compatibility with the long-term conservation of this resource.

10. We reserve the authority to immediately suspend or revoke any permit if we find that the State has not adhered to the terms and conditions specified in 50 CFR 13.27 and 13.28 or if we determine that the State's population of resident Canada geese no longer poses a threat to human health or safety, to personal property, or of injury to other interests.

Before establishing the special Canada goose permit, we conducted an analysis of the environmental effects and a lengthy public involvement process. The process began with a September 3, 1996, notice of availability of a ''Draft Environmental Assessment (DEA) on Permits for Control of Injurious Canada Geese and Request for Comments on Potential Regulations'', we published in the **Federal Register** (61 FR 46431). The notice advised the public that we had prepared a DEA and announced our intent to consider regulatory changes to the process for issuance of permits to control injurious resident Canada geese. We subsequently extended the public comment period on November 12, 1996 (61 FR 58084). As a result of this invitation for public comment, we received 101 comments including two from Federal agencies, 28 from State wildlife agencies, 24 from private organizations and 47 from private citizens. After consideration of the comments, we revised our DEA.

On March 31, 1998, we published in the **Federal Register** (63 FR 15698) a proposal to establish a Canada goose damage management program (*i.e.*, Special Canada Goose Permit). In response to our proposed rule, we received 465 comments from Federal, State and local agencies, non-governmental organizations, and individuals. In addition, we received several petitions containing 1,674 signatures. Based on review and evaluation of comments by the public and information contained in the Environmental Assessment, we revised the final rule and determined that the action to establish a special Canada goose permit program for the control and management of resident Canada geese would not be a major Federal action that would significantly affect the quality of the human environment within the meaning of Section 102(2)(c) of the National Environmental Policy Act of 1969. Accordingly, we made a Finding of No Significant Impact on this action and determined that preparation of an Environmental Impact Statement was not required. The EA and Finding of No Significant Impact are available to the public at the location indicated under the **ADDRESSES** caption.

We believe the new special permits established by the June 17 rule further results in biologically sound and more cost-effective and efficient resident Canada goose damage management. Overall, the new permit will provide some additional management flexibility needed to address this serious problem and at the same time simplify the procedures needed to administer this program. In the short term, we believe this permit will satisfy the need for an efficient/cost-effective program while allowing us to maintain management control. To date, several States have applied for the new permits.

Alternatives

We are considering the following alternatives. After the scoping process, we will develop the alternatives to be included in the EIS and base them on the mission of the Service and comments received during scoping. We are soliciting your comments on issues, alternatives, and impacts to be addressed in the EIS.

A. No Action Alternative

Under the No Action Alternative, no additional regulatory methods or strategies would be authorized. We would continue the use of special hunting seasons, the issuance of depredation permits, and the issuance of special Canada goose permits. These permits would continue to be issued under existing regulations.

For each of the next 5 alternatives, as a baseline for comparison, we would continue the use of special hunting seasons, the issuance of depredation permits, and the issuance of special Canada goose permits. All of these permits would continue to be issued under existing regulations.

B. Increased Promotion of Non-Lethal Control and Management

Under this alternative, we would actively promote the increased use of non-lethal management tools, such as habitat manipulation and management, harassment techniques, and trapping and relocation. While permits would continue to be issued under existing regulations, no additional regulatory methods or strategies would be introduced.

C. Nest and Egg Depredation Order

This alternative would provide a direct population control strategy for resident Canada goose breeding areas in the U.S. This alternative would establish a depredation order authorizing States to implement a program allowing the take of nests and eggs to stabilize resident Canada goose populations without threatening their long-term health. Monitoring and evaluation programs are in place, or would be required, to estimate population sizes and prevent populations from falling below either the lower management thresholds established by Flyway Councils, or individual State population objectives. Since the goal of this alternative would be to stabilize breeding populations, not direct reduction, no appreciable reduction in the numbers of adult Canada geese would likely occur.

D. Depredation Order for Health and Human Safety

This alternative would establish a depredation order authorizing States to establish and implement a program allowing the take of resident Canada goose adults, goslings, nests and eggs from populations posing threats to health and human safety. The intent of this alternative is to significantly reduce or stabilize resident Canada goose populations at areas such as airports, water supply reservoirs, and other such areas, where there is a demonstrated threat to health and human safety, without threatening the population's long-term health. Monitoring and evaluation programs are in place, or would be required, to estimate population sizes and prevent populations from falling below either the lower management thresholds established by Flyway Councils, or individual State population objectives. Under this alternative, some appreciable localized reductions in the numbers of adult geese could occur.

E. Conservation Order

This alternative would authorize direct population control strategies such as nest and egg destruction, gosling and adult trapping and culling programs, or other general population reduction strategies on resident Canada goose populations in the U.S. This alternative would establish a conservation order authorizing States to develop and implement a program allowing the take of geese posing threats to health and human safety and damaging personal and public property. The intent of this

alternative is to significantly reduce or stabilize resident Canada goose populations at areas where conflicts are occurring without threatening the long-term health of the overall population. Monitoring and evaluation programs are in place, or would be required, to estimate population sizes and prevent populations from falling below either the lower management thresholds established by Flyway Councils, or individual State population objectives. State breeding populations would be monitored annually each spring to determine the maximum allowable take under the conservation order. Under this alternative, some appreciable localized reductions in the numbers of adult geese would likely occur and lesser overall population reductions could occur.

F. General Depredation Order

This alternative would authorize direct population control strategies such as nest and egg destruction, gosling and adult trapping and culling programs, or other general population reduction strategies on resident Canada goose populations in the U.S. This alternative would establish a depredation order allowing any authorized person to take geese posing threats to health and human safety and damaging personal and public property. The intent of this alternative is to significantly reduce resident Canada goose populations at areas where conflicts are occurring. Monitoring and evaluation programs are in place, or would be required, to estimate population sizes and prevent populations from falling below either the lower management thresholds established by Flyway Councils, or individual State population objectives. Under this alternative, some appreciable localized reductions in the numbers of adult geese would likely occur and lesser overall population reductions could occur.

	No action	Increased promotion of non-lethal control	Nest and egg depredation order	Health and human safety depredation order	Conservation order	General depredation order
Continued use of Special seasons.	Yes	Yes	Yes	Yes	Yes	Yes.
Continued use of Depredation permits.	Yes	Yes	Yes	Yes	Yes	Yes.
Continued use of Special Canada goose permits.	Yes	Yes	Yes	Yes	Yes	Yes.
Promotion of non-lethal control and management.	Yes	Yes	Yes	Yes	Yes	Yes.
Goal: Reduction or stabilization of population.	Stabilization	Stabilization	Stabilization	Both	Both	Both.
Additional take of nests and eggs.	No	No	Yes	Yes	Yes	Yes.
Additional take of adults and goslings.	No	No	No	Yes	Yes	Yes.
Additional population monitoring.	No	No	Yes	Yes	Yes	Yes.
Implementation authority given to.	n/a	n/a	States	States	States	Affected parties.

Issue Resolution and Environmental Review

The primary issue to be addressed during the scoping and planning process for the EIS is to determine which management alternatives for the control of resident Canada goose populations will be analyzed. We will prepare a discussion of the potential effect, by alternative, which will include the following areas:

(1) Resident Canada goose populations and their habitats.

(2) Human health and safety.

(3) Public and private property damage and conflicts.

(4) Sport hunting opportunities.

(5) Socioeconomic effects.

We will conduct the environmental review of the management action in accordance with the requirements of the National Environmental Policy Act, as appropriate. We are furnishing this Notice in accordance with 40 CFR 1501.7, to obtain suggestions and information from other agencies, tribes, and the public on the scope of issues to be addressed in the EIS. A draft EIS should be available to the public in the spring of 2000.

Public Scoping Meetings

A schedule of public scoping meeting dates, locations, and times is not available at this time. We will publish a notice of any such meetings in the **Federal Register**.

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Dated: August 11, 1999.

John G. Rogers,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 99–21472 Filed 8–18–99; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–010–1430–01; MTM 84895]

Notice of Closure of Public Land to the Use of Motorized Vehicles and the Discharge of Firearms

AGENCY: Bureau of Land Management, Interior

ACTION: Closure of 379.9 acres of public land to the use of motorized vehicles and the discharge of firearms.

SUMMARY: Notice is served that public land south of Laurel, Montana known as the Sundance Lodge Recreation Area (formerly the Altman Ranch), is closed to the use of motorized, off-highway vehicles (OHVs), and the discharge of any firearm including pellet guns, unless permitted by the authorized officer, Billings Field Office. This closure will remain in effect until public consultation is complete and an activity plan for the area is approved. OHV use includes all types of motor vehicles except for those authorized for administrative operations for farming and property maintenance or other BLM management programs. The area will remain open as a walk-in area for archery hunting, hiking, picnicking, cross-country skiing, bicycling, horseback riding, and wildlife watching. This closure is necessary to protect the public land, adjoining private property, and for public safety. The public land protected by this closure is located at:

Sundance Lodge Recreation Area

Principal Meridian, Montana

T. 2 S., R. 24 E.,
Sec. 22: Lots 5, and 6;
Sec. 23: Lots 3, and 4 excluding Tract 1 as described in Certificate of Survey #1750, Lots 2, 5, 7, 8, 10, and N2SW;
Sec. 24: Lot 2 excluding Tract 1 as described in Certificate of Survey #1750.

Containing 379.9 acres.

FOR FURTHER INFORMATION CONTACT: Sandra S. Brooks, Field Manager, BLM, Billings Field Office, PO Box 36800, Billings, Montana 59107–6800 or call 406–896–5013.

SUPPLEMENTARY INFORMATION: Authority for this action is outlined in sections 302, 303, and 310 of the Federal Land Policy and Management Act of October 21, 1976 (43 U.S.C. 1716) and Title 43 Code of Federal Regulations Part 8341 (43 CFR 8341.2) and 8364 (43 CFR 8364.1). Any person who fails to comply with this closure is subject to arrest and a fine up to $1,000 or imprisonment not to exceed 12 months, or both. This closure applies to all persons except persons authorized by the Bureau of Land Management.

Dated: August 12, 1999.

Sandra S. Brooks,

Field Manager.

[FR Doc. 99–21570 Filed 8–18–99; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Availability; Record of Decision, Marsh-Billings-Rockefeller National Historical Park

AGENCY: National Park Service, Interior.

ACTION: The National Park Service announces the availability of the Record of Decision of the Final Impact Statement for the Marsh-Billings-Rockefeller National Historical Park General Management Plan.

SUMMARY: The National Park Service has prepared the Record of Decision of the Final Environmental Impact Statement for the Marsh-Billings-Rockefeller National Historical Park General Management Plan pursuant to the National Environmental Policy Act of 1969 and the regulations promulgated by the Council on Environmental Quality at 40 CFR 1505.2. A Record of Decision is a concise statement of the decision made, the basis for the decision, and the background of the project, including the decision making process, other alternatives considered, and public involvement. Concurrent with adopting this Record of Decision on the Final Environmental Impact Statement, Marsh-Billings-Rockefeller National Historical Park General Management Plan is approved.

The National Park Service began planning for the management of Marsh-Billings-Rockefeller National Historical Park in 1993. The National Park Service presented and evaluated two management scenarios (the Proposal and the Alternative) in a Draft General Management Plan/Draft Environmental Impact Statement. The draft plan underwent sixty days of public and interagency review. After considering public and agency comment, the National Park Service produced the Final Environmental Impact Statement, which was available to the public for thirty days beginning on June 23, 1999. The National Park Service took no action for the thirty-day period of public availability, after which time the Park Service prepared the Record of Decision, selecting the Proposal as the final plan. The Record of Decision is now approved and available to the public.

Availability: Copies of the Record of Decision are available at Marsh-Billings-Rockefeller National Historical Park, 54 Elm Street, Woodstock, Vermont. For further information, please contact the Superintendent, Marsh-Billings-Rockefeller National Historical Park, PO Box 178, Woodstock, Vermont 05091; voice at (802) 457–3368; fax at (802) 457–3405.

Dated: August 6, 1999.

Marie Rust,

Director, Northeast Region.

[FR Doc. 99–21509 Filed 8–18–99; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF THE INTERIOR

National Park Service

General Management Plan, Environmental Impact Statement, Devils Tower National Monument, Wyoming

AGENCY: National Park Service, DOI.

ACTION: Notice of intent to prepare an environmental impact statement for the General Management Plan, Devils Tower National Monument.

SUMMARY: Under the provisions of the National Environmental Policy Act, the National Park Service is preparing an environmental impact statement for the General Management Plan for Devils Tower National Monument.

The effort will result in a comprehensive general management plan that prescribes the resource conditions and visitor experiences that are to be achieved and maintained in the park over time. The clarification of what must be achieved according to law and policy will be based on review of the park's purpose, significance, special mandates, and the body of laws and

policies directing park management. Management decisions to be made where law, policy, or regulations do not provide clear guidance or limits will be based on the purposes of the monument, the range of public expectations and concerns, resource analysis, an evaluation of the natural, cultural, and social impacts of alternative courses of action, and consideration of long-term economic costs. Based on determinations of desired conditions, the plan will outline the kinds of resource management activities, visitor activities, and development that would be appropriate in the monument in the future. Alternatives will be developed through this planning process and will include, at a minimum, no-action and the preferred alternative.

Major issues include health and vitality of natural and cultural resources, adequacy of interpretive programs, park aesthetics, overall visitor and traffic congestion, and boundary concerns.

A scoping newsletter has been prepared that details the issues identified to date. Copies of that information can be obtained from the Planning Team, Devils Tower NM, P.O. Box 10, Devils Tower, Wyoming 82714–0010, 307–467–5283, extension 12.

FOR FURTHER INFORMATION CONTACT: Contact the Planning Team, Devils Tower NM at the above address and telephone number.

Dated: July 30, 1999.

R. Everhart,

Director, Intermountain Region.

[FR Doc. 99–21220 Filed 8–18–99; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

Acadia National Park Advisory Commission; Notice of Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770, 5 U.S.C. App. 1, sec. 10), that the Acadia National Park Advisory Commission will hold a meeting on Monday, September 13, 1999.

The Commission was established pursuant to Public Law 99–420, section 103. The purpose of the commission is to consult with the Secretary of the Interior, or his designee, on matters relating to the management and development of the park, including but not limited to the acquisition of lands and interests in lands (including conservation easements on islands) and termination of rights of use and occupancy.

The meeting will convene at park Headquarters, McFarland Hill, Bar Harbor, Maine, at 1:30 p.m. to consider the following agenda:

1. Review and approval of minutes from the meeting held July 12, 1999
2. Committee reports
   Land Conservation
   Education
   Part Use
   Science
   Nomination—nomination of officers
3. Old business
4. Superintendent's report
5. Public comments
6. Proposed agenda and date of next Commission meeting

The meeting is open to the public. Interested persons may make oral/written presentations to the Commission or file written statements. Such requests should be made to the Superintendent at least seven days prior to the meeting.

Further information concerning this meeting may be obtained from the Superintendent, Acadia National Park, P.O. Box 177, Bar Harbor, Maine 04609, tel: (207) 288–3338.

Dated: August 12, 1999.

Paul F. Haertel,

Superintendent, Acadia National Park.

[FR Doc. 99–21510 Filed 8–18–99; 8:45 am]

BILLING CODE 4310–70–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–814 (Final)]

Creatine Monohydrate From China

AGENCY: United States International Trade Commission.

ACTION: Scheduling of the final phase of an antidumping investigation.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping investigation No. 731–TA–814 (Final) under section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act) to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of less-than-fair-value imports from China of creatine monohydrate,[1] provided for in subheading 2925.20.90 of the Harmonized Tariff Schedule of the United States.

For further information concerning the conduct of this phase of the investigation, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

EFFECTIVE DATE: July 30, 1999.

FOR FURTHER INFORMATION CONTACT: Cynthia Trainor (202–205–3354), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (http://www.usitc.gov).

SUPPLEMENTARY INFORMATION:

Background

The final phase of this investigation is being scheduled as a result of an affirmative preliminary determination by the Department of Commerce that imports of creatine monohydrate from China are being sold in the United States at less than fair value within the meaning of section 733 of the Act (19 U.S.C. 1673b). The investigation was requested in a petition filed on February 12, 1999, by Pfanstiehl Laboratories, Inc., Waukegan, IL.

Participation in the Investigation and Public Service List

Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of this investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigation need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigation.

[1] Creatine monohydrate, with the chemical name of N-(aminoiminomethyl)-N-methylglycine, is commonly referred to as ''creatine.'' In its pure form creatine is a white, tasteless, odorless powder that is a naturally occurring metabolite found in muscle tissue. The Chemical Abstracts Service registry number for creatine monohydrate is 6020–87–7.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and BPI Service List

Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of this investigation available to authorized applicants under the APO issued in the investigation, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigation. A party granted access to BPI in the preliminary phase of the investigation need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff Report

The prehearing staff report in the final phase of this investigation will be placed in the nonpublic record on December 2, 1999, and a public version will be issued thereafter, pursuant to section 207.22 of the Commission's rules.

Hearing

The Commission will hold a hearing in connection with the final phase of this investigation beginning at 9:30 a.m. on December 16, 1999, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before December 1, 1999. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on December 6, 1999, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 days prior to the date of the hearing.

Written Submissions

Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.23 of the Commission's rules; the deadline for filing is December 9, 1999. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.25 of the Commission's rules. The deadline for filing posthearing briefs is December 23, 1999; witness testimony must be filed no later than three days before the hearing. In addition, any person who has not entered an appearance as a party to the investigation may submit a written statement of information pertinent to the subject of the investigation on or before December 23, 1999. On January 11, 2000, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before January 13, 2000, but such final comments must not contain new factual information and must otherwise comply with section 207.30 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This investigation is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

Issued: August 13, 1999.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 99–21535 Filed 8–18–99; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 701–TA–253 and 731–TA–132, 252, 271, 273, 276–277, 296, 409–410, 532–534, and 536–537 (Review)]

Certain Pipe and Tube From Argentina, Brazil, Canada, India, Korea, Mexico, Singapore, Taiwan, Thailand, Turkey, and Venezuela

AGENCY: United States International Trade Commission.

ACTION: Notice of Commission determinations to conduct full five-year reviews concerning the countervailing duty and antidumping duty orders on certain pipe and tube from Argentina, Brazil, Canada, India, Korea, Mexico, Singapore, Taiwan, Thailand, Turkey, and Venezuela.

SUMMARY: The Commission hereby gives notice that it will proceed with full reviews pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)) to determine whether revocation of the countervailing duty and antidumping duty orders on certain pipe and tube from Argentina, Brazil, Canada, India, Korea, Mexico, Singapore, Taiwan, Thailand, Turkey, and Venezuela would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. The Commission has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B); a schedule for the reviews will be established and announced at a later date.

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207). Recent amendments to the Rules of Practice and Procedure pertinent to five-year reviews, including the text of subpart F of part 207, are published at 63 FR 30599, June 5, 1998, and may be downloaded from the Commission's World Wide Web site at http://www.usitc.gov/rules.htm.

EFFECTIVE DATE: August 5, 1999.

FOR FURTHER INFORMATION CONTACT: Bonnie Noreen (202–205–3167), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the

Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (http://www.usitc.gov).

SUPPLEMENTARY INFORMATION: On August 5, 1999, the Commission determined that it should proceed to full reviews in the subject five-year reviews pursuant to section 751(c)(5) of the Act. The Commission, in consultation with the Department of Commerce, grouped these reviews because they involve similar domestic like products. See 19 U.S.C. 1675(c)(5)(D); 63 FR 29372, 29374 (May 29, 1998).

With regard to all subject pipe and tube from Canada, Korea, Mexico, Turkey, and Venezuela, the Commission found that both the domestic and respondent interested party group responses to its notice of institution [1] were adequate and voted to conduct full reviews.

With regard to all subject pipe and tube from Argentina, Brazil, India, Singapore, Taiwan, and Thailand, the Commission found that the domestic interested party groups were adequate [2] and the respondent interested party group responses were inadequate. The Commission also found that other circumstances warranted conducting full reviews. [3]

A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's web site.

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

Issued: August 13, 1999.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 99–21534 Filed 8–18–99; 8:45 am]

BILLING CODE 7020–02–P

[1] The notice of institution for all of the subject reviews was published in the **Federal Register** on May 3, 1999 (64 FR 23679).

[2] Commissioner Crawford dissenting with respect to small diameter rectangular pipe and tube from Singapore and light-walled rectangular tube from Argentina and Taiwan.

[3] Chairman Bragg and Commissioner Crawford dissenting with respect to small diameter rectangular pipe and tube from Singapore and light-walled rectangular tube from Argentina and Taiwan. Commissioner Crawford also dissented with respect to oil country tubular goods from Taiwan.

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Clean Water Act

Notice is hereby given that on July 29, 1999, a proposed First Amended Consent Decree (''Decree'') in *United States of America and the State of Georgia* v. *The City of Atlanta, Georgia,* Civil Action No. 1:98–CV–1956–TWT was lodged with the United States District Court for the Northern District of Georgia. This Decree represents a settlement of claims against the City of Atlanta, Georgia under Section 309(b) and (d) of the Clean Water Act, 33 U.S.C. 1319(b) and (d).

The settlement is entitled First Amended Consent Decree. However, while it imposes additional burdens on the parties, it does not change any of the obligations set forth in the Consent Decree entered by the Court on September 24, 1998.

Under this settlement between United States, the State and the City, the City will be required to undertake extensive rehabilitation to its sewer collection system and its wastewater treatment facilities. The consent decree also provides for the recovery of civil penalties of $700,000 to be paid by the City. The penalty shall be paid as follows: within sixty (60) days after the Decree is entered by the Court, the City shall pay $125,000 to the United States, and $125,000 to the State of Georgia, on or before the one (1) year anniversary of the Date of Entry of the Decree, the City shall pay $125,000 to the United States and $125,000 to the State of Georgia. The City shall also pay the State $100,000 within sixty (60) days of the date of entry, along with $100,000 on or before the one (1) year anniversary of the Decree.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed First Amended Consent Decree. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States of America and State of Georgia* v. *City of Atlanta, Georgia,* Civil Action No. 1:98–CV–1956–TWT, D.J. Ref. 90–5–1–1–4430.

The proposed Decree may be examined at the Office of the United States Attorney, Northern District of Georgia, 1800 United States Courthouse, 75 Spring Street, S.W., Atlanta, Georgia 30335 and at Region 4, Office of the Environmental Protection Agency, Water Programs Enforcement Branch, Water Management Division, Atlanta Federal Center, 61 Forsyth Street S.W., Atlanta, Georgia 30303–3104, and at the Consent Decree Library, 1120 G Street, NW, 4th Floor, Washington, DC 20005, (202) 624–0892. A copy of the proposed Decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, NW, 3rd Floor, Washington, DC 20005. In requesting a copy, please enclosed a check in the amount of $37.75 (25 cents per page reproduction cost) payable to the Consent Decree Library.

Joel Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 99–21557 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

[AAG/A Order No. 171–99]

Privacy Act of 1974; Notice of Cancellation of Two FBI Systems of Records

Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), notice is given that the Department of Justice, Federal Bureau of Investigation (FBI), is canceling the following systems of records:

Routine Correspondence Handled By Predesigned Form, JUSTICE/FBI–004 (last published in the **Federal Register** on October 5, 1993, at 58 FR 51873); and

Routine Correspondence Prepared Without File Copy, JUSTICE/FBI–005 (last published in the **Federal Register** on October 5, 1993, at 58 FR 51873).

The FBI has determined that these systems are no longer being used and that the records that formerly constituted the system no longer exist. The records have been disposed of in due course under FBI Records management authority. Therefore, the FBI has decided to cancel these two systems of records.

This deletion of the affected record system notices is not with the purview of subsection (r) of the Privacy Act, 5 U.S.C. 552a, which requires the submission of a new or altered system report to the Office of Management and Budget and congressional committees.

Dated: August 6, 1999.

Stephen R. Colgate,

Assistant Attorney General for Administration.

[FR Doc. 99–21558 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–CJ–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—The Asymmetrical Digital Subscriber Line Forum

Notice is hereby given that on June 10, 1998, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), The Asymmetrical Digital Subscriber Line Forum (''ADSL'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plantiffs to actual damages under specified circumstances. Specifically, Amphenol Canada, Scarborough, Ontario, CANADA; Centillium Technology, Fremont, CA; Concentric Network, Cupertino, CA: DS2 (Design of Systems on Silicon), Valencia, SPAIN; Digi International, Minnetonka, MN; Flowpoint, Los Gastos, CA; GenRad, Westford, MA; ITRI, Taiwan, REPUBLIC OF CHINA; Integrated Telecom Express, Santa Clara, CA; Intrakom S.A., Peania, Attika, GREECE; Iterated Systems, Atlanta, GA; LSI Logic, Milpitas, CA; Next Level Communications, Parsippany, NJ; Matsushita Electric Industrial, Osaka, JAPAN; Helsinki Telephone, Helsinki, FINLAND; Objective Systems, Red Bank, NJ; NTT, Chiba, JAPAN; Madge Networks, Wexham, ENGLAND; Rockwell Semiconductor, Pacific Palisades, CA; SAT (Sagem Group), Paris, FRANCE; Sonera Corporation, Helinski, FINLAND; Tektronic, Chelmsford, MA; Teledata Systems, Herzlia, Pituach, ISRAEL, Telrad, LOD, ISRAEL, Toshiba, Tokyo, JAPAN; Transcend Access, Fremont, CA; UUNET, Fairfax, VA; ViaGate Technologies, Bridgewater, NJ; Web Silicon, Los Gatos, CA; and Virata Ltd., Santa Clara, CA have been added as parties to this venture. Also, ATM Ltd., Santa Clara, CA has been dropped as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and ADSL intends to file additional written notifications disclosing all changes in membership.

On May 15, 1995, ADSL filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 25, 1995 (60 FR 38058).

The last notification was filed with the Department on March 20, 1998. A notice of this filing has not yet been published in the **Federal Register**.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc 99–21561 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cargill, Inc. and Osmonics, Inc

Notice is hereby given that, on February 2, 1999, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Cargill, Inc. and Osmonics, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identifies of the parties and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to Section 6(b) of the Act, the identities of the parties are Cargill, Inc., Wayzata, MN; and Osmonics, Inc., Minnetonka, MN. The nature and objectives of the venture are to develop solvent compatible membrane systems for liquid separations.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 99–21564 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Center for Waste Reduction Technologies (''CWRT''): Total Cost Accounting Project

Notice is hereby given that, on June 3, 1999, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Center for Waste Reduction Technologies (''CWRT''): Total Cost Accounting Project has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, General Electric Corporation, Schenectady, NY; ICI Americas, Inc., Wilmington, DE; Minnesota Mining and Manufacturing Company, St. Paul, MN; Rhone Poulenc North America, Monmouth Junction, NJ; and Union Carbide Corporation, Danbury, CT have been dropped as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remain open, and Center for Waste Reduction Technologies (''CWRT''): Total Cost Accounting Project intends to file additional written notification disclosing all changes in membership.

On April 23, 1997, Center for Waste Reduction Technologies (''CWRT''): Total Cost Accounting Project filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on November 28, 1997 (62 FR 63386).

The last notification was filed with the Department on June 11, 1998. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on November 2, 1998 (63 FR 58787).

Information regarding participation in this joint venture may be obtained from: Center for Waste Reduction Technologies, American Institute of Chemical Engineers, 3 Park Avenue, New York, NY 10016.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 99–21559 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Center for Waste Reduction Technologies (''CWRT''): Novel Reactor Design Project

Notice is hereby given that, on June 3, 1999, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Center for Waste Reduction Technologies (''CWRT''): Novel Reactor Design Project has filed written notifications simultaneously with the Attorney General and the

Federal Trade Commission disclosing changes in its membership status. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, ARCO Chemical Company, Newton Square, PA; Monsanto Company, St. Louis, MO; and Proctor & Gamble Co., Cincinnati, OH have been dropped as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Center for Waste Reduction Technologies (''CWRT''): Novel Reactor Design Project intends to file additional written notification disclosing all changes in membership.

On December 19, 1995, Center for Waste Reduction Technologies (''CWRT''): Novel Reactor Design Project filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on February 12, 1996 (61 FR 5409).

The last notification was filed with the Department on June 11, 1998. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on November 2, 1998 (63 FR 58786).

Information regarding participation in this joint venture may be obtained from: Center for Waste Reduction Technologies, American Institute of Chemical Engineers, 3 Park Avenue, New York, NY 10016.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 99–21565 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—GE Corporation Research and Development

Notice is hereby given that, on November 5, 1998, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), GE Corporate Research & Development has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to Section 6(b) of the Act, the identities of the parties are GE Corporate Research and Development, Niskayuna, NY; NBC4 WRC–TV, Washington, DC; Comark Communications, Inc., Southwick, MA; and Thomson Consumer Electronics, Indianapolis, IN. The nature and objectives of the venture are to develop and demonstrate improved HDTV/DTV receivers, receiver antennas, and broadcast transmitters, while staying within the limits of the ATSC standard.

The activities of this venture project will be partially funded by an award from the Advanced Technology Program, National Institute of Standards and Technology, Department of Commerce.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 99–21562 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Joint Industry Program—Development of an Instrument for Corrosion Detection in Insulated Pipes Using a Magnetostrictive Sensor

Notice is hereby given that, on January 27, 1999, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Joint Industry Program—Development of an Instrument for Corrosion Detection in Insulated Pipes Using a Magnetostrictive Sensor has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Hanil General Corporation, Kwanak-Ku, KOREA has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Joint Industry Program—Development of an Instrument for Corrosion Detection in Insulated Pipes Using a Magnetostrictive Sensor intends to file additional written notification disclosing all changes in membership.

On October 19, 1995, Joint Industry Program—Development of an Instrument for Corrosion Detection in Insulated Pipes Using a Magnetostrictive Sensor filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act of February 23, 1996 961 FR 7020).

The last notification was filed with the Department on March 23, 1998. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on December 30, 1998 (63 FR 71955–71956).

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 99–21560 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Wireless Application Protocol Forum, Ltd.

Notice is hereby given that, on May 13, 1998, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Wireless Application Protocol Forum, Ltd. (''WAP'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Apion Ltd Interpoint, Belfast, NORTHERN IRELAND; Certicom Corp., San Mateo, CA; DeLaRue Card Systems, Basingstoke, UNITED KINGDOM; Deutsche Telekom Mobilnet GmbH, Bonn, GERMANY; Fujitsu Software Corporation, San Jose, CA; Geoworks Corporation, Alameda, CA; Hongkong Telecom CSL, Hong Kong, HONG KONG; IBM Corporation, Yorktown Heights, NY; Matsushita Communication Industrial Co., Ltd., Yokohama, JAPAN; MD-Co, Kontich, BELGIUM; NTT Mobile Communications Network Inc., Kangawa, JAPAN; Psion Software plc, London, ENGLAND; Samsung Electronics Co., Ltd., Suwon City, KOREA; Scandinavian Softline Technology Oy, Espoo, FINLAND;

Schlumberger Industries S.A., Montrouge, FRANCE; Sema Group Limited, North York, Ontario, CANADA; Sendit AB (publ), Stockholm, SWEDEN; Societe Francaise du Radio Telephone, Paris, FRANCE; Spyglass, Inc., Naperville, IL; Starfish Software, Inc., Scotts Valley, CA; Telecom Finland Ltd., Tele, FINLAND; Telecom Italia Mobile S.p.A., Torino, ITALY; Uniden San Diego Research & Development Center, Inc., San Diego, CA; Vodafone Limited, Newbury, Berkshire, UNITED KINGDOM; and VTT Information Technology, Helsinki, FINLAND have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and WAP intends to file additional written notifications disclosing all changes in membership.

On March 18, 1998, WAP filed its original notification pursuant to Section 6(a) of the Act. A notice for this filing has not yet been published in the **Federal Register**.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 99–21563 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Sworn statement of refugee applying for admission to the United States.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on May 5, 1999 at 64 FR 24187, allowing for emergency OMB review and approval and a 60-day public comment period. No public comment was received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 20, 1999. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, Department of Justice Desk Officer, Room 10235, Washington, DC 20530; 202–395–7316.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhances the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) Type of Information Collection: Extension of a currently approved collection.

(2) Title of the Form/Collection: Sworn Statement of Refugee Applying for Admission to the United States.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form G–646. Office of International Affairs, Immigration and Naturalization Service.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individual or households. This form provides the grounds of admissibility to the United States as they apply to refugees. The information collected allows INS to make admissibility determinations for refugees.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 75,000 responses at 30 minutes (.50 hours) per response.

(6) An estimate of the total public burden (in hours) associated with the collection: 37,500 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: August 10, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–21511 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Application for replacement naturalization/citizenship document.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on February 19, 1999 at 64 FR 8405, allowing for a 60-day public comment period. No public comment was received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 20, 1999. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this

notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, Department of Justice Desk Officer, Room 10235, Washington, DC 20530; 202–395–7316.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

Overview of this information collection:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) Type of Information Collection: Reinstatement without change of a previously approved collection.

(2) Title of the Form/Collection: Application for Replacement Naturalization/Citizenship Document.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form N–565. Office of Naturalization Operations, Immigration and Naturalization Service.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals or households. This form is used by the INS to determine the applicant's eligibility for a replacement of a Declaration of Intention, Naturalization Certificate, Certificate of Citizenship or Repatriation Certificate that was lost, mutilated or destroyed, or if the applicant's name was changed by marriage or by court order after issuance of original document. This form may also be used to apply for special certificate of naturalization as a U.S. citizen to be recognized by a foreign country.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 22,567 responses at 55 minutes (0.916) hours per response.

(6) An estimate of the total public burden (in hours) associated with the collection:

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the items(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: August 10, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–21512 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Guarantee of payment.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on February 23, 1999 at 64 FR 8860, allowing for a 60-day public comment period. No public comment was received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 20, 1999. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, Department of Justice Desk Officer, Room 10235, Washington, DC 20530; 202–395–7316.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) Type of Information Collection: Reinstatement without change of previously approved collection.

(2) Title of the Form/Collection: Guarantee of Payment.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form I–510. Detention and Deportation Division, Immigration and Naturalization Service.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Business or other for-profit. Section 253 of the Immigration and Nationality Act (INA) provides that the master or agent of a vessel or aircraft shall guarantee payment for expenses incurred for an alien crewman who arrived in the United States and is afflicted with any disease or illness mentioned in Section 255 of the Act.

(5) An estimate of the total number of respondents and the amount of time

estimated for an average respondent to respond: 100 responses at 5 minutes (.083) hours per response.

(6) An estimate of the total public burden (in hours) associated with the collection: 8 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: August 10, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–21513 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Affidavit of financial support and intent to petition for legal custody for Public Law 97–359 Amerasian.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on February 25, 1999 at 64 FR 9350, allowing for a 60-day public comment period. No public comment was received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 20, 1999. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, Department of Justice Desk Officer, Room 10235, Washington, DC 20530; 202–395–7316.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) Type of Information Collection: Reinstatement without change of a previously approved collection.

(2) Title of the Form/Collection: Affidavit of Financial Support and Intent to Petition for Legal Custody for Public Law 97–359 Amerasian.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form I–361. Adjudications Division, Immigration and Naturalization Service.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals or households. This form will be used in support of Form I–360 to assure financial support for Public Law 97–359 Amerasian.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 50 responses at 30 minutes (0.5) hours per response.

(6) An estimate of the total public burden (in hours) associated with the collection: 25 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW, Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: August 10, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–21514 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Petition for approval of school for attendance by nonimmigrant students.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on February 25, 1999 at 64 FR 9349, allowing for a 60-day public comment period. No public comment was received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged

and will be accepted until September 20, 1999. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, Department of Justice Desk Officer, Room 10235, Washington, DC 20530; 202–395–7316.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collection; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) Type of Information Collection: Reinstatement without change of a previously approved collection.

(2) Title of the Form/Collection: Petition for Approval of School for Attendance by Nonimmigrant Students.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form I–17. Adjudications Division, Immigration and Naturalization Service.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Business or other for-profit. The information is used by learning institutions to determine acceptance of nonimmigrant students, as well as INS to establish a list of names and locations of schools or campuses within school systems or districts with multiple locations, which schools are bona fide institutions of learning.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 322 responses at one (1) hour per response.

(6) An estimate of the total public burden (in hours) associated with the collection: 322 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: August 10, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–21515 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Application to adjust status from temporary to permanent resident.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on April 12, 1999 at 64 FR 17681, allowing for a 60-day public comment period. No public comment was received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 20, 1999. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burdens and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, Department of Justice Desk Officer, Room 10235, Washington, DC 20530; 202–395–7316.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) Type of Information Collection: Reinstatement without change of a previously approved collection.

(2) Title of Form/Collection: Application to Adjust Status from Temporary to Permanent Resident.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form I–698. Adjudication Division, Immigration and Naturalization Service.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals or households. In compliance with Pub. L. 99–604 and Pub. L. 100–204, Section 902, the Service will accept and review applications from temporary resident aliens to adjust their status to permanent residence. This form will collect the necessary information to

adjudicate the application and issue an Alien Registration Card (I–551).

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 1,179 responses at 1 hour per response.

(6) An estimate of the total public burden (in hours) associated with the collection: 1,179 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: August 10, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–21516 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Memorandum of understanding to participate in Employment Eligibility Confirmation Pilot Program.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on March 18, 1999 at 64 FR 13448. The notice requested emergency OMB review and approval with a 60-day public comment period. No public comment was received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 20, 1999. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, Department of Justice Desk Officer, Room 10235, Washington, DC 20530; 202–395–7316.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) Type of Information Collection: Extension of a previously approved collection.

(2) Title of the Form/Collection: Memorandum of Understanding to Participate in an Employment Eligibility Confirmation Pilot Program.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: No Agency Form Number (File No. OMB–18). SAVE Program, Immigration and Naturalization Service.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Businesses or other for-profit. The employer data collected from the Memorandum of Understanding (MOU) enables the INS to collect employer information for each site that will be performing verification queries. The MOU also provides the terms and conditions governing the pilots.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 4,000 responses at 1.5 hours per response.

(6) An estimate of the total public burden (in hours) associated with the collection: 22,161 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: August 11, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–21517 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Application for permission to reapply for admission into the United States after deportation or removal.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in

accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on April 1, 1999 at 64 FR 15816, allowing for a 60–day public comment period. No public comment was received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 20, 1999. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, Department of Justice Desk Officer, Room 10235, Washington, DC 20530; 202–395–7316.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Reinstatement without change of a previously approved collection.

(2) *Title of the Form/Collection:* Application for Permission to Reapply for Admission into the United States after Deportation or Removal.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–212. Adjudications Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. This form provides information to be used by the Immigration and Naturalization Service to determine eligibility for a waiver for an inadmissible alien who is applying for a visa to enter the United States after deportation, removal or departure, as provided for under section 212 of the Immigration and Naturalization Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 7,250 responses at 20 minutes (.333) hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 2,414 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW, Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: August 10, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–21518 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Health and Human Services statistical data for refugee/asylee adjusting status.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on April 1, 1999 at 64 FR 15816, allowing for a 60-day public comment period. No public comment was received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 20, 1999. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, Department of Justice Desk Officer, Room 10235, Washington, DC 20530; 202–395–7316.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Reinstatement without change of a previously approved collection.

(2) *Title of the Form/Collection:* Health and Human Services Statistical Data for Refugee/Asylee Adjusting Status.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the*

collection: Form I–643. Office of International Affairs, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. The primary purpose of the data collection on this form is for use in the Office of Refugee Resettlement Report to Congress (8 U.S.C. 1523). The Service is required to report on the status of refugees at the time of adjustment to lawful permanent resident.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 195,000 responses at 10 minutes (.166 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 32,370 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW., Washington, DC 20530.

Dated: August 10, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–21519 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Petition by entrepreneur to remove conditions.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on June 1, 1999 at 64 FR 29361. The notice allowed for a 60-day public comment period. No public comment was received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 20, 1999. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, Department of Justice Desk Officer, Room 10235, Washington, DC 20530; 202–395–7316.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Reinstatement of a previously approved collection.

(2) *Title of the Form/Collection:* Petition by Entrepreneur to Remove Conditions.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–829. Adjudications Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. This form is used by a conditional resident alien entrepreneur who obtained such status through a qualifying investment, to apply to remove the conditions on his or her conditional resident status.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 200 responses at 65 minutes (1.08 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 216 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: August 10, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–21520 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Alien address report card.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the

Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** April 15, 1999 at 64 FR 18636, allowing for a 60-day public comment period. No public comment was received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 20, 1999. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, Department of Justice Desk Officer, Room 10235, Washington, DC 20530; 202–395–7316.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(2) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Reinstatement without change of a previously approved collection.

(2) *Title of the Form/Collection:* Alien Address Report Card.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–104, Adjudications Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individual or households. The form is used by aliens to report their current address, upon a ten-day notice, only when required by the Attorney General under section 265 of the Immigration and Nationality Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1 responses at 5 minutes (.083 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW., Washington, DC 20530.

Dated: August 10, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–21521 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Certificate of satisfactory pursuit.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on April 15, 1999 at 64 FR 18636, allowing for a 60-day public comment period. No public comment was received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 20, 1999. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, Department of Justice Desk Officer, Room 10235, Washington, DC 20530; 202–395–7316.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Reinstatement without change of a previously approved collection.

(2) *Title of the Form/Collection:* Certificate of Satisfactory Pursuit.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–699. Adjudications Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. The Service will use this

form to verify that a certified course provider has supplied the required instructions to temporary resident aliens, in compliance with Public Law 99–603 and Public Law 100–204, section 902.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 100,000 responses at 10 minutes (0.166 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 16,600 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: August 10, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–21522 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Notice of information collection under review: Registration for classification as refugee.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on June 2, 1999 at 64 FR 29671, allowing for a 60-day public comment period. No public comment was received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 20, 1999. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, Department of Justice Desk Officer, Room 10235, Washington, DC 20530; 202–395–7316.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection*: Extension of a currently approved collection.

(2) *Title of the Form/Collection*: Registration for Classification as Refugee.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection*: Form I–590. Office of International Affairs, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract*: Primary: Individuals or Households. This information collection provides a uniform method for applicants to apply for refugee status and contains the information needed in order to adjudicate such applications.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond*: 140,000 responses at 35 minutes (.583 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection*: 81,620 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: August 10, 1999.

Ricard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service

[FR Doc. 99–21523 Filed 8–18–99; 8:45 am]

BILLING CODE 4410–10–M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. STN 50–454 and STN 50–455]

Commonwealth Edison Company; Notice of Partial Denial of Amendments to Facility Operating Licenses and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) has partially denied a request by Commonwealth Edison Company (ComEd, the licensee) for amendments to Facility Operating License Nos. NPF–37 and NPF–66, issued to ComEd for operation of Byron Station, Unit Nos. 1 and 2, located in Ogle County, Illinois. Notice of Consideration of Issuance of these amendments was published in the **Federal Register** on April 22, 1998 (63 FR 19966).

The purpose of the licensee's amendment request was to delete license conditions which have been satisfied, revise others to delete parts which are no longer applicable or to revise references, and make editorial changes.

The NRC staff has concluded that a portion of the request, related to the proposed deletion of dates for approved security plans, can not be granted. The basis for the denial is detailed in the Safety Evaluation related to Amendment Nos. 110 and 110 dated August 10, 1999.

By September 20, 1999, the licensee may demand a hearing with respect to the partial denial described above. Any person whose interest may be affected by this proceeding may file a written petition for leave to intervene.

A request for hearing or petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date.

A copy of any petitions should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and to Ms. Pamela B. Stroebel, Senior Vice President and General Counsel, Commonwealth Edison Company, P.O. Box 767, Chicago, Illinois 60690–0767, attorney for the licensee.

For further details with respect to this action, see (1) the application for amendments dated March 14, 1997, (2) Amendment Nos. 110 and 110 to Facility Operating License Nos. NPR–37 and NPR–66, and (3) the Commission's related Safety Evaluation and Environmental Assessment.

These documents are 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 Byron Public Library District, 109 N. Franklin, P.O. Box 434, Byron, Illinois 61010.

Dated at Rockville, Maryland, this 10th day of August 1999.

For the Nuclear Regulatory Commission.

Suzanne C. Black,

Acting Director, Project Directorate III, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 99–21529 Filed 8–18–99; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–754]

Consideration of License Renewal Request for the General Electric Vallecitos Nuclear Center and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission is considering renewal of Materials License SNM–960 which was issued to the General Electric Vallecitos Nuclear Center on February 8, 1994. The Materials License is for the operation of their Laboratory and General Services Operations facility in Sunol, California. The renewal application requests authorization to receive and possess special nuclear material and to use special nuclear material in research and development activities involving chemical and physical analysis. The license renewal application is dated January 21, 1999, and is available for public inspection at the NRC's Public Document Room, the Gelman Building, 2120 L Street NW, Washington, DC 20555.

Prior to approving the renewal application, NRC will have made findings required by the Atomic Energy Act of 1954, as amended, and NRC's regulations. These findings will be documented in a Safety Evaluation Report. The renewal of the licensee will be documented in the issuance of a renewed SNM–960 license.

The NRC hereby provides notice that this is a proceeding on an application for renewal of a license falling within the scope of Subpart L, ''Informal Hearing Procedure for Adjudication in Materials Licensing Proceedings,'' of NRC's rules and practice for domestic licensing processing in 10 CFR Part 2. Pursuant to Section 2.1205(a), any person whose interest may be affected by this proceeding may file a request for a hearing in accordance with Section 2.1205(d). A request for a hearing must be filed within thirty (30) days of the date of publication of the **Federal Register** notice.

The request for a hearing must be filed with the Office of Secretary either:

1. By delivery to the Rulemakings and Adjudications Branch of the Secretary at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852–2738; or

2. By mail or telegram addressed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Attention: Rulemakings and Adjudications Branch.

In addition to meeting other applicable requirements to 10 CFR Part 2 of the NRC's regulations, a request for a hearing filed by a person other than the applicant must describe in detail:

1. The interest of the requester in the proceeding;

2. How that interest may be affected by the results of the proceeding, including the reasons why the requestor should be permitted a hearing, with particular reference to the factors set out in Section 2.1205(h).

3. The requester's areas of concern about the licensing activity that is the subject matter of the proceeding; and

4. The circumstances establishing that the request for a hearing is timely in accordance with Section 2.1205(d).

In accordance with 10 CFR Section 2.1205(f), each request for a hearing must also be served, by delivering it personally or by mail to:

1. The applicant, General Electric Company, Vallecitos Nuclear Center, 6705 Vallecitos Road, (State Route 84) Sunol, California 94586; Attention Mr. Ben Murray; and

2. The NRC staff, by delivering to the Executive Director for Operations, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, or by mail, addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Any hearing that is requested and granted will be held in accordance with the NRC's Informal Hearing Procedures for Adjustications in Material Licensing Proceedings in 10 CFR Part 2, Subpart L.

For further details with respect to this action see the application for renewal dated January 21, 1999. This document is available for public inspection at the NRC's Public Document Room, 2120 L Street N.W., Washington, DC 20555. Questions should be referred to the NRC's project manager for the General Electric Vallecitos Nuclear Center, Andrew D. Rayland, at (301) 415–8102.

Dated at Rockville, Maryland, this 12th day of August 1999.

For the Nuclear Regulatory Commission.

Theodore S. Sherr,

Chief, Licensing and International Safeguards Branch, Division of Fuel Cycle Safety and Safeguards, NMSS.

[FR Doc. 99–21530 Filed 8–18–99; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–461]

Illinois Power Company; Notice of Consideration of Approval of Transfer of Facility Operating License and Issuance of Conforming Amendment and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an order under 10 CFR 50.80 approving the transfer of Facility Operating License No. NPF–62 for the Clinton Power Station (CPS) currently held by Illinois Power Company (IP, or the licensee). The transfer would be to AmerGen Energy Company, LLC (AmerGen). The Commission is also considering amending the license for administrative purposes to reflect the proposed transfer.

Under the proposed transfer, AmerGen would be authorized to possess, use, and operate CPS under essentially the same conditions and authorizations included in the existing license. In addition, no physical changes will be made to CPS as a result of the proposed transfer, and there will be no significant changes in the day-to-day operations of CPS. Antitrust conditions of the CPS license are proposed to be deleted because, among other things, they apply to IP which will no longer be the licensee.

Pursuant to 10 CFR 50.80, no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission shall give its consent in writing. The Commission will approve an application for the transfer of a license, if the Commission determines that the proposed transferee is qualified to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

Before issuance of the proposed conforming license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

As provided in 10 CFR 2.1315, unless otherwise determined by the Commission with regard to a specific application, the Commission has determined that any amendment to the license of a utilization facility which does no more than conform the license to reflect the transfer action involves no significant hazards consideration. No contrary determination has been made with respect to this specific license amendment application. In light of the generic determination reflected in 10 CFR 2.1315, no public comments with respect to significant hazards considerations are being solicited, notwithstanding the general comment procedures contained in 10 CFR 50.91.

The filing of requests for hearing and petitions for leave to intervene, and written comments with regard to the license transfer application, are discussed below.

By September 8, 1999, any person whose interest may be affected by the Commission's action on the application may request a hearing, and, if not the applicants, may petition for leave to intervene in a hearing procedure on the Commission's action. Requests for a hearing and petitions for leave to intervene should be filed in accordance with the Commission's rules of practice set forth in Subpart M, ''Public Notification, Availability of Documents and Records, Hearing Requests and Procedures for Hearings on License Transfer Applications,'' of 10 CFR Part 2. In particular, such requests must comply with the requirements set forth in 10 CFR 2.1306, and should address the considerations contained in 10 CFR 2.1308(a). Untimely requests and petitions may be denied, as provided in 10 CFR 2.1308(b), unless good cause for failure to file on time is established. In addition, an untimely request or petition should address the factors that the Commission will also consider, in reviewing untimely requests or petitions, set forth in 10 CFR 2.1308(b)(1)–(2).

Requests for a hearing and petitions for leave to intervene should be served upon John Lamberski, counsel for IP, at Troutman Sanders LLP, 600 Peachtree Street, N.E., suite 5200, NationsBank Plaza, Atlanta, Georgia 30308–2216 (tel: 404–885–3360; fax: 404–962–6610; e-mail: *john.lamberski@troutmansanders.com*) and Kevin P. Gallen, counsel for AmerGen, at Morgan, Lewis & Bockius LLP, 1800 M Street, NW, Washington, DC 20036–5869 (tel: 202–467–7462; fax: 202–467–7176; e-mail: *kpgallen@mlb.com*); the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 (e-mail address for filings regarding license transfer cases only: *OGCLT@NRC.gov*); and the Secretary of the Commission, U. S. Nuclear Regulatory Commission, Washington, D.C., 20555–0001, Attention: Rulemakings and Adjudications Staff, in accordance with 10 CFR 2.1313.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

As an alternative to requests for hearing and petitions to intervene, by September 20, 1999, persons may submit written comments regarding the license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute partof the decisional record. Comments should be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and should cite the publication date and page number of this **Federal Register** notice.

For further details with respect to this action, see the application dated July 23, 1999, 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 Vespasian Warner Public Library, 310 N. Quincy Street, Clinton, IL 61727.

Dated at Rockville, Maryland, this 12th day of August 1999.

For the Nuclear Regulatory Commission.

Jon B. Hopkins,

Senior Project Manager, Section 2, Project Directorate III, Division of Licensing Projects Management, Office of Nuclear Reactor Regulation.

[FR Doc. 99–21532 Filed 8–18–99; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–7580]

Finding of No Significant Impact for Proposed Decommissioning Activity at the Fansteel Facility in Muskogee, OK

The U.S. Nuclear Regulatory Commission (NRC) is considering an amendment to Source Material License No. SMB–911 for approval of a decommissioning plan to remediate for unrestricted use under the Site Decommissioning Management Plan (SDMP) Action Plan (57 FR 13389) of the Eastern Property Area of the Fansteel, Inc., (Fansteel) facility in Muskogee, Oklahoma. This area covers approximately 56.6 acres of the site and is defined in Revised Figure 3 of Fansteel's submittal dated July 16, 1999.

Summary of the Environmental Assessment

Identification of the Proposed Action

The proposed action is approval of a decommissioning plan to remediate the Eastern Property Area, approximately 56.6 acres, of the Fansteel site for unrestricted use under the SDMP Action Plan. Currently, Fansteel is in active operation to reprocess onsite waste residues from previous metal extraction operations to recover tantalum, niobium, scandium, and other rare earth elements for commercial use. These residues contain natural uranium and thorium in sufficient quantities to be classified as a source material by the NRC. Reprocessing operations take place on the Eastern Property Area of the site and are expected to continue for approximately 11 years. Initial decommissioning activities involving waste reduction, soil remediation, and groundwater treatment are scheduled to take place concurrently with operations. Final decommissioning activities are proposed to take place after 11 years, or after reprocessing operations have ceased. The entire decommissioning process is estimated to be a 13 year project.

Need for the Proposed Action

Fansteel requests the proposed action to remove radioactive contamination from areas of land, groundwater, buildings, and equipment located on the Eastern Property Area of Fansteel's facility in Muskogee, Oklahoma.

Environmental Impacts of the Proposed Action

The radiological impacts resulting from the proposed action involve the release of air and water effluents, which may contain low levels of residual radioactive contamination, to the environment. These effluents will occur during the various decommissioning activities such as excavation of soils, dismantlement of buildings, waste management, and transportation of wastes. The release of radioactive materials in air and water effluents will be within the regulatory limits set forth in 10 CFR Part 20, Appendix B.

The non-radiological impacts resulting from the proposed action are not expected to be significant. Land use, air quality, surface water quality, and groundwater quality are expected to be improved. Industrial safety will be maintained under the existing safety program for operations. Ambient noise and traffic around the site will not increase substantially over that present for operations. No known threatened or endangered plants or animals are known to occur at the Fansteel site. There will be no disproportionally high or adverse effects or impacts on minority or low-income populations.

Alternatives to the Proposed Action

There are two alternatives to the proposed Action:

1. No action and continued surveillance and maintenance of the contaminated soil, groundwater, and facilities; and

2. Decommissioning under the radiological dose criteria of the new License Termination Rule (Subpart E to 10 CFR Part 20).

The first alternative is inconsistent with NRC's requirements for timely decommissioning as described in 10 CFR 40.42(h)(1). Fansteel has requested an exemption from the second alternative as is permitted by the general provisions of 10 CFR 20.1401(b)(3).

Agencies and Persons Consulted

The Oklahoma Department of Environmental Quality (OKDEQ) and the Office of the Attorney General (OAG) of the State of Oklahoma were consulted concerning this proposed action.

Conclusion

The NRC has determined that the proposed decommissioning plan will not result in significant impact to human health or the environment.

Finding of No Significant Impact

The Commission has prepared an Environmental Assessment (EA) related to the amendment of Source Material License SMB–911. On the basis of the EA, the Commission has concluded that environmental impacts associated with the proposed action would not be significant and do not warrant the preparation of an Environmental Impact Statement. Accordingly, it has been determined that a Finding of No Significant Impact is appropriate.

The EA and other documents related to this proposed action are available for public inspection and copying at the Commission's Public Document Room at the Gelman Building, 2120 L Street NW, Washington, DC 20555. Questions should be referred to the NRC's Project Manager for Fansteel, Michael E. Adjodha, at 301–415–8147 or by electronic mail at mea1@nrc.gov.

Dated at Rockville, Maryland, this 12th day of August 1999.

For the Nuclear Regulatory Commission.

Theodore S. Sherr,

Chief, Licensing and International Safeguards Branch, Division of Fuel Cycle Safety and Safeguards, NMSS.

[FR Doc. 99–21531 Filed 8–18–99; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF MANAGEMENT AND BUDGET

1999 List of Designated Federal Entities and Federal Entities

AGENCY: Office of Management and Budget

ACTION: Notice.

SUMMARY: This notice provides a list of Designated Federal Entities and Federal Entities, as required by the Inspector General Act of 1978 (IG Act), as amended.

FOR FURTHER INFORMATION CONTACT: Sheila Conley or Tawana Webb at 202–395-6911, Office of Federal Financial Management, Office of Management and Budget.

SUPPLEMENTARY INFORMATION: This notice provides a copy of the 1999 List of Designated Federal Entities and Federal Entities, which the Office of Management and Budget (OMB) is required to publish annually under the IG Act. This list is also posted on the Inspector General community's website, IGNET, at http://www.ignet.gov.

The List is divided into two groups: Designated Federal Entities and Federal Entities. The Designated Federal Entities are required to establish and maintain Offices of Inspector General. The Designated Federal Entities are listed in the IG Act, except that those agencies which have ceased to exist have been deleted from the list.

Federal Entities are required to report annually to each House of Congress and OMB on audit and investigative activities in their organizations. Federal Entities are defined as ''any Government corporation (within the meaning of section 103(1) of title 5, United States Code), any Government controlled corporation (within the meaning of section 103(2) of such title), or any other entity in the Executive Branch of government, or any independent regulatory agency'' other than the Executive Office of the President and agencies with statutory Inspectors General. There are 3 deletions and 2 additions in the 1999 list of Designated Federal Entities and Federal Entities from the 1998 list published in the July 10, 1998, **Federal Register** (63 FR 37421).

The 1999 List of Designated Federal Entities and Federal Entities was prepared in consultation with the U.S. General Accounting Office.

Norwood J. Jackson, Jr.,

Acting Controller, Office of Federal Financial Management.

Herein follows the text of the 1999 List of Designated Federal Entities and Federal Entities:

1999 List of Designated Federal Entities and Federal Entities

The Inspector General Act of 1978, as amended, requires Office of Management Budget (OMB) to publish a list of ''Designated Federal Entities'' and ''Federal Entities'' and the heads of such entities. Designated Federal Entities were required to establish Offices of Inspector General before April 17, 1989. Federal Entities are required to report annually to each House of Congress and the OMB on audit and investigative activities in their organizations.

Designated Federal Entities and Entity Heads

1. Amtrak—President
2. Appalachian Regional Commission—Federal Co-Chairperson
3. The Board of Governors, Federal Reserve System—Chairperson
4. Commodity Futures Trading Commission—Chairperson
5. Consumer Product Safety Commission—Chairperson
6. Corporation for Public Broadcasting—Board of Directors
7. Equal Employment Opportunity Commission—Chairperson
8. Farm Credit Administration—Chairperson
9. Federal Communications Commission—Chairperson
10. Federal Election Commission—Chairperson
11. Federal Housing Finance Board—Chairperson
12. Federal Labor Relations Authority—Chairperson
13. Federal Maritime Commission—Chairperson
14. Federal Trade Commission—Chairperson
15. Legal Services Corporation—Board of Directors
16. National Archives and Records Administration—Archivist of the United States
17. National Credit Union Administration—Chairperson
18. National Endowment for the Arts—Chairperson
19. National Endowment for the Humanities—Chairperson
20. National Labor Relations Board—Chairperson
21. National Science Foundation—National Science Board
22. Panama Canal Commission—Chairperson
23. Peace Corps—Director
24. Pension Benefit Guaranty Corporation—Chairperson
25. Securities and Exchange Commission—Chairperson
26. Smithsonian Institution—Secretary
27. Tennessee Valley Authority—Board of Directors
28. United States International Trade Commission—Chairperson
29. United States Postal Service—Governors of the Postal Service

Federal Entities and Entity Heads

1. Advisory Council on Historic Preservation—Chairperson
2. African Development Foundation—Chairperson
3. American Battle Monuments Commission—Chairperson
4. Architectural and Transportation Barriers Compliance Board—Chairperson
5. Armed Forces Retirement Home—Board of Directors
6. Barry Goldwater Scholarship and Excellence in Education Foundation—Chairperson
7. Chemical Safety and Hazard Investigation Board—Chairperson
8. Christopher Columbus Fellowship Foundation—Chairperson
9. Commission for the Preservation of America's Heritage Abroad—Chairperson
10. Commission of Fine Arts—Chairperson
11. Commission on Civil Rights—Chairperson
12. Committee for Purchase from People Who Are Blind or Severely Disabled—Chairperson
13. Court of Veterans Appeal—Chief Judge
14. Defense Nuclear Facilities Safety Board—Chairperson
15. Denali Commission—Chairperson
16. Export-Import Bank—President and Chairperson
17. Farm Credit System Financial Assistance Corporation—Chairperson
18. Farm Credit System Insurance Corporation—Chairperson
19. Federal Financial Institutions Examination Council Appraisal Subcommittee—Chairperson
20. Federal Mediation and Conciliation Service—Director
21. Federal Mine Safety and Health Review Commission—Chairperson
22. Federal Retirement Thrift Investment Board—Executive Director
23. Harry S Truman Scholarship Foundation—Chairperson
24. Institute of American Indian and Alaska Native Culture and Arts Development—Chairperson
25. Institute of Museum and Library Services—Director
26. Intelligence Community Management Account—Deputy Director of Central Intelligence for Community Management
27. Inter-American Foundation—Chairperson
28. James Madison Memorial Fellowship Foundation—Chairperson
29. Japan-U.S. Friendship Commission—Chairperson
30. Marine Mammal Commission—Chairperson
31. Merit Systems Protection Board—Chairperson
32. Morris K. Udall Scholarship and Excellence in National Environmental Policy Foundation—Chairperson
33. National Capital Planning Commission—Chairperson
34. National Commission on Libraries and Information Science—Chairperson
35. National Council on Disability—Chairperson
36. National Education Goals Panel—Chairperson
37. National Mediation Board—Chairperson
38. National Transportation Safety Board—Chairperson
39. Neighborhood Reinvestment Corporation—Chairperson
40. Nuclear Waste Technical Review Board—Chairperson
41. Occupational Safety and Health Review Commission—Chairperson
42. Office of Government Ethics—Director
43. Office of Navajo and Hopi Indian Relocation—Chairperson
44. Office of Special Counsel—Special Counsel
45. Offices of Independent Counsel—Independent Counsels
46. Overseas Private Investment Corporation—Board of Directors
47. Postal Rate Commission—Chairperson
48. Presidio Trust—Chairperson
49. Selective Service System—Director
50. Smithsonian Institution/John F. Kennedy Center for the Performing Arts—Chairperson
51. Smithsonian Institution/National Gallery of Art—President
52. Smithsonian Institution/Woodrow Wilson International Center for Scholars—Director
53. State Justice Institute—Director
54. Trade and Development Agency—Director
55. U.S. Holocaust Memorial Council—Chairperson

56. U.S. Institute of Peace—Chairperson

[FR Doc. 99–21486 Filed 8–18–99; 8:45 am]

BILLING CODE 3110–01–P

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–23946; 812–11368]

Allied Capital Corporation; Notice of Application

August 12, 1999.

AGENCY: Securities and Exchange Commission (the ''SEC'' or the ''Commission'').

ACTION: Notice of application for an order under section 61(a)(3)(B) of the Investment Company Act of 1940 (the ''Act'').

Summary of Application: Applicant, Allied Capital Corporation, requests an order approving its stock option plan (the ''Plan'') to grant options to directors who are neither employees nor officers of applicant (the ''Eligible Directors'').

Filing Dates: The application was filed on October 20, 1998, and amended on April 28, 1999. Applicant has agreed to file an amendment, the substance of which is incorporated in this notice, during the notice period.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 on September 7, 1999, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, NW, Washington, DC 20549–0609. Applicant, 1919 Pennsylvania Avenue, NW, Washington, DC 20006–3434.

FOR FURTHER INFORMATION CONTACT: Elaine M. Boggs, Senior Counsel, at (202) 942–0572, or Christine Y. Greenlees, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch, 450 5th Street, NW, Washington, DC 20549–0102 (tel. (202) 942–8090).

Applicant's Representations

1. Applicant is a business development company (''BDC'') within the meaning of section 2(a)(48) of the Act.[1] Applicant's primary business is making loans and investments in small and medium-sized companies. Applicant's investment decisions are made by its management in accordance with policies approved by applicant's board of directors (the ''Board''). Applicant does not have an external investment adviser within the meaning of section 2(a)(20) of the Act.

2. Applicant requests an order under section 61(a)(3)(B) of the Act approving the Plan for Eligible Directors, including each new Eligible Director who may be appointed in the future to the Board. Applicant has a twelve member Board, ten of whom are Eligible Directors.[2] None of the Eligible Directors is an ''interested person,'' as defined in section 2(a)(19) of the Act, of applicant.

3. The Plan was approved by the Board on September 29, 1997, and approved by applicant's shareholders on November 26, 1997. The Board has implemented part of the Plan with respect to applicant's officers and employee directors. The portion of the Plan applicable to Eligible Directors will not be implemented until an order is received from the Commission approving that portion of the Plan.

4. The Plan provides that each Eligible Director serving at the time the requested order is issued, and each new Eligible Director at the time he or she joins the Board, will be entitled to receive options to purchase 10,000 shares. Thereafter, incumbent Eligible Directors will be awarded options to purchase 5,000 shares each year. Options may be granted under the Plan for a maximum of 6,250,000 shares, which is approximately 12% of applicant's current outstanding shares. Applicant has no warrants, options, or rights to purchase its voting stock outstanding other than those issued pursuant to the Plan.

5. The exercise price of the options will be the closing price of applicant's common stock on the Nasdaq National Market, or on the exchange where applicant's shares are traded, on the date the option is granted. Each option states the period or periods of time within which the option may be exercised by the optionee, which may not exceed ten years from the date the option is granted. All rights to exercise options will terminate 60 days after an Eligible Director ceases to be a director for any reason other than death or permanent disability. If an Eligible Director dies or becomes permanently disabled, the Eligible Directors estate may exercise his or her options during the one-year period following the date of death or permanent disability. Options will not be transferable other than by will or the laws of descent and distribution. In the future, the Plan may be amended to permit options to be transferable pursuant to a qualified domestic relations order (''QDRO'') as defined by section 414(p) of the Internal Revenue Code of 1986, as amended (the ''Code'').[3]

6. Applicant's compensation committee (the ''Committee'') will administer the Plan. The Committee, which currently has four members, is and will be comprised of members of the Board who (a) are non-employee directors; (b) have no financial interest in grants of stock options to applicant's officers under the Plan; and (c) are not ''interested persons,'' as defined in section 2(a)(19) of the Act, of applicant. Decisions by the Committee are subject to review and approval by the full Board. The Plan may be modified, revised, or terminated by the Board at any time. The Board is permitted to make any modifications or revisions to any provision of the Plan without shareholder approval except with respect to the number of shares underlying options authorized for issuance under the Plan. The Plan as it relates to grants of options to Eligible Directors will not be modified materially from the description in the application without obtaining an order of the Commission or approval of the Commission staff.

[1] Section 2(a)(48) defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in sections 55(a)(1) through 55(a)(3) of the Act and makes available significant managerial assistance with respect to the issuers of the securities.

[2] Each of applicant's Eligible Directors receives $1,000 for each meeting of the Board attended. In addition, members of the executive committee of the Board receive annual compensation of $10,000. Eligible Directors receive no other compensation for their services to applicant.

[3] Applicant states that a QDRO is made pursuant to a court order or decree under state domestic relations law (*e.g.*, involving divorce, child support, alimony, or marital property rights). Under section 414(p) of the Code, a QDRO permits as state domestic relations court to issue orders that will allow for employee plan benefits to be paid to an alternate payee.

Applicant's Legal Analysis

1. Section 61(a)(3)(B) of the Act provides, in pertinent part, that a BDC may issue to its Eligible Directors options to purchase its voting securities pursuant to an executive compensation plan, provided that: (a) the options expire by their terms within 10 years; (b) the exercise price of the options is not less than the current market value of the underlying securities at the date of the issuance of the options, or if no market exists, the current net asset value of the voting securities; (c) the proposal to issue the options is authorized by the BDC's shareholders, and is approved by order of the SEC on the basis that the terms of the proposal are fair and reasonable and does not involve overreaching of the BDC or its shareholders; (d) the options are not transferable except for disposition by gift, will, or intestacy; (e) no investment adviser of the BDC receives any compensation described in paragraph (1) of section 205 of the Investment Advisers Act of 1940, except to the extent permitted by clause (A) or (B) of that section; and (f) the BDC does not have a profit-sharing plan as described in section 57(n) of the Act.

2. In addition, section 61(a)(3)(B) of the Act provides that the amount of the BDC's voting securities that would result from the exercise of all outstanding warrants, options, and rights at the time of issuance may not exceed 25% of the BDC's outstanding voting securities, except that if the amount of voting securities that would result from the exercise of all outstanding warrants, options, and rights issued to the BDC's directors, officers, and employees pursuant to an executive compensation plan would exceed 15% of the BDC's outstanding voting securities, then the total amount of voting securities that would result from the exercise of all outstanding warrants, options, and rights at the time of issuance will not exceed 20% of the outstanding voting securities of the BDC.

3. Applicant states that the terms of the Plan meet all the requirements of section 61(a)(3)(B) of the Act. Applicant states that the number of voting securities that would result from the exercise of all options issued or issuable to officers and non-officer directors under the Plan is 6,250,000 shares, or 12% of the company's outstanding stock. The total number of shares of applicant's common stock issuable under the Plan that may be granted in any one year to current Eligible Directors represents about .08% of applicant's outstanding common stock. Applicant states that given the small number of shares of common stock issuable upon exercise of the options, the exercise of the options pursuant to the Plan will not have a substantial dilutive effect on the net asset value of applicant's common stock.

4. Applicant submits that the terms of the Plan are fair and reasonable and do not involve overreaching of applicant or its shareholders. Applicant states that the Eligible Directors are actively involved in the management and oversight of applicant's business and operations and are likely to have specific experience with respect to industries in which applicant makes a significant number of investments. Applicant asserts that the options will have value only to the extent that applicant's market value increases above the exercise price of the options, which will encourage the Eligible Directors to remain on the Board and to devote their best efforts to the success of applicant's business. In addition, applicant states that the Plan will assist it in attracting qualified persons to serve as Eligible Directors in future. Applicant further states that the options will provide a means for the Eligible Directors to increase their ownership interests in applicant, thereby ensuring close identification of their interests with the interests of applicant and its shareholders.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–21485 Filed 8–18–99; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–41735; File No. SR–Amex–99–24]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the American Stock Exchange LLC Relating to the Amendment of Commentary .01 to Exchange Rule 340 and Amendment of Exchange Rule 590

August 12, 1999.

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 9, 1999, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the 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 text of the proposed rule change is available at the Office of the Secretary, the Amex and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Amex included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Amex has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In 1993, the New York Stock Exchange (''NYSE'') amended its rules to require all clerks to submit their fingerprints and Forms U–4 as a prerequisite to admission to the trading floor.[3] The intent of the rule was to prevent an individual subject to a statutory disqualification from being employed on the exchange. At the same time, the NYSE required employers to report the termination of a clerk on Form U–5. The NYSE also amended its rules to provide for the imposition of a $1,000 fine on members and member organizations that failed to comply with the NYSE's floor clerical personnel procedures.[4] The Amex currently requires candidates for membership to be fingerprinted and complete Form U–4, but does not impose a similar requirement on clerks. The Amex also does not require members and member

[1] 15 U.S.C. 78s (b)(1).

[2] 17 CFR 240.19b–4

[3] NYSE Rule 35, Supplementary Material .50 and .60. *See* Securities Exchange Act Release No. 33045 (October 14, 1993), 58 FR 54179 (October 20, 1993) (File No. SR–NYSE–93–28).

[4] *See* Securities Exchange Act Release No. 32422 (June 7, 1993), 58 FR 32972 (June 14, 1993) (File No. SR–NYSE–93–14).

organizations to report terminations of clerks.

The Exchange now proposes to amend Commentary .01 to Amex Rule 340 to require all current and prospective clerks to be fingerprinted and submit Form U–4.[5] Fingerprints will be submitted to the Department of Justice for a fingerprint report. All existing clerks will have eight weeks from the date the proposed rule change becomes operative to supply their fingerprints to the Exchange and submit a completed Form U–4. After the proposed rule changes become operative, new clerks and temporary clerks will not be permitted on the trading floor until they have been fingerprinted and submitted a Form U–4. A charge for the fingerprinting will be assessed against the clerk's employer.[6] The Exchange also proposes that members and member organizations must report the discharge or termination of any clerk to the Exchange on Form U–5. Members and member organizations will be responsible for obtaining and submitting a terminated clerk's Amex identification badge with the Form U–5 to the Exchange's Membership Services Department.

Members and member organizations that fail, or whose employees fail, to submit the required fingerprints, Form U–4s and Form U–5s within the stipulated times face disciplinary action by the Exchange. In this regard, the Exchange proposes to amend the Minor Fine Plan (Amex Rule 590) to add failure to timely submit Form U–5s to the list of infractions that may be disciplined under part 3 of the Rule. This provides that members and member organizations may be fined $50 per day for the late filing of required reports. Part 1 of the Minor Fine Plan also will be amended to provide fines for the employers of clerks that do not submit fingerprints and Form U–4s within the required time frame after the Rule becomes operative. The minimum fines under Part 1 of Rule 590 is $500 for individuals and $1,000 for member organizations.

The purpose of the proposed rule change is to establish better control over admission to the trading and to ensure that only qualified persons have floor access.

[5] In the event that a clerk has already been fingerprinted and filed a U–4, the Exchange will accept in lieu of a new U–4 and fingerprints, a copy of the most recent fingerprint report and a written statement from his or her firm's compliance officer or employer/member that the U–4 is current and no reportable events have occurred.

[6] The current charges are $9.60 to have fingerprints taken and $25.50 for processing by the Department of Justice.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act[7] in general and further the objectives of Section 6(b)(5)[8] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and are not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

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.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Chance and Timing for Commission Action

Because the foregoing proposed rule change: (1) does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not become operative for 30 days after the date of filing or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and subparagraph (f)(6) of Rule 19b-4 thereunder.[10]

At any time within 60 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, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the Amex. All submissions should refer to File No. SR–Amex–99–24 and should be submitted by September 9, 1999.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–21539 Filed 8–18–99; 8:45 am]

BILING CODE 8010–01–M

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–41736; File No. SR–OCC–99–8]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Fees and Charges

August 12, 1999.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on July 27, 1999, The Options Clearing Corporation (''OCC'') 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 OCC. The Commission is publishing this notice to solicit comments from interested persons on the proposed rule change.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change reduces OCC clearing fees for established products in the second half of 1999.

[1] 15 U.S.C. 78s(b)(1).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC 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. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to reduce the clearing fees charged for established products in the second half of 1999. OCC experienced a record volume of options cleared during the first two quarters of 1999. As a result, OCC proposes to reduce its level of clearing fees, effective July 1, 1999, as follows:

Contract trade level	Current clearing fee	Proposed clearing fee
1–500	$0.09	$0.075
501–1000	0.07	0.06
1001–2000	0.06	0.0525
>2000	*110.00	*100.00

*Flat fee.

OCC believes that the foregoing fee change will assure each clearing member a discount on clearing fees. The proposed fee schedule change will also allow clearing members to immediately realize the benefits of reduced fees (rather than waiting for OCC's rebate of clearing fees) without adversely affecting OCC's ability to maintain an acceptable level of retained earnings. The clearing fees will revert to their current levels on the first trading day of year 2000.

OCC believes that the proposed rule change is consistent with Section 17A of the Act[3] and the rules and regulations thereunder because it benefits OCC's clearing members by reducing fees and allocating fees among clearing members in an equitable manner.

(B) Self-Regulatory Organization's Statement on Burden on Competition

OCC does not believe that the proposed rule change would impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

Written comments were not and are not intended to be solicited with respect to the proposed rule change, and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(iii)[4] of the Act and pursuant to Rule 19b–4(f)(2)[5] promulgated thereunder because the proposal establishes or changes a due, fee, or other charge imposed by OCC. At any time within sixty days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549–0609. 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. 20549–0609. Copies of such filing also will be available for inspection and copying at the principal office of OCC. All submissions should refer to File No. SR–OCC–99–8 and should be submitted by September 9, 1999.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–21538 Filed 8–18–99; 8:45 am]

BILLING CODE 8010–01–M

[2] The Commission has modified the text of the summaries prepared by OCC.

[3] 15 U.S.C. 78q–1.

[4] 15 U.S.C. 78s(b)(3)(A)(iii).

[5] 17 CFR 240.19b–4(f)(2).

[6] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

Privacy Act 1974; Computer Matching Program (Agreement for SSA/Federal Bureau of Prisons (BOP) Match of Prisoner Data, Match #1041)

AGENCY: Social Security Administration (SSA).

ACTION: Notice of Computer Matching Program.

SUMMARY: In accordance with the provisions of the Privacy Act, as amended, this notice announces a computer matching program that SSA plans to conduct.

DATES: SSA will file a report of the subject matching program with the Committee on Governmental Affairs of the Senate, the Committee on Government Reform and Oversight of the House of Representatives and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). The matching program will be effective as indicated below.

ADDRESSES: Interested parties may comment on this notice by either facsimile to (410) 597–0841 or writing to the Associate Commissioner for Program Support, 4400 West High Rise Building, 6401 Security Boulevard, Baltimore, MD 21235–6401. All comments received will be available for public inspection at this address.

FOR FURTHER INFORMATION CONTACT: The Associate Commissioner for Program Support at the above address.

SUPPLEMENTARY INFORMATION:

A. General

The Computer Matching and Privacy Protection Act of 1988 (Public Law (Pub. L.) 100–503), amended the Privacy Act (5 U.S.C. 552a) by establishing the conditions under which computer matching involving the Federal Government could be performed and adding certain protection for individuals applying for or receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) further amended the Privacy Act regarding protection for such individuals.

The Privacy Act, as amended, regulates the use of computer matching

by Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain approval of the match agreements by any appropriate Federal agency Data Integrity Boards;

(3) Furnish detailed reports about matching programs to Congress and OMB;

(4) Notify applicants and beneficiaries that their records are subject to matching; and

(5) Verify match findings before reducing, suspending, terminating or denying an individual's benefits or payments.

B. SSA Computer Matches Subject to the Privacy Act

We have taken action to ensure that all of SSA's computer matching programs comply with the requirements of the Privacy Act, as amended.

Dated: July 29, 1999.

Susan M. Daniels, Ph.D.,

Deputy Commissioner for Disability and Income Security Programs.

Notice of Computer Matching Program, Federal Bureau of Prisons (BOP) With SSA.

A. Participating Agencies

SSA and BOP.

B. Purpose of the Matching Program

Sections 202(x)(1) and 202(x)(3) of the Social Security Act (the Act), codified at 42 U.S.C. 402(x)(1) and 402(x)(3) prohibit SSA from paying old-age, survivors, and disability insurance benefits to incarcerated individuals under title II of the Act. Section 1611(e)(1)(A) of the Act, codified at 42 U.S.C. 1382(e)(1)(A), provides, with some exceptions, that inmates in public institutions are not eligible for payments in the Supplemental Security Income (SSI) program under title XVI of the Act. Sections 205(j)(1)(A), 205(j)(5), 1631(a)(2)(A)(iii) and 1631 (a)(2)(E), codified at 42 U.S.C., 405(j)(1)(A), 405(j)(5), 1383(g)(2)(A)(iii) and 1383(a)(2)(E) require SSA to revoke certification for payment of benefits to representative payees under certain circumstances and to investigate and monitor the performance of representative payees. The incarceration or confinement of a representative payee is a circumstance highly relevant to SSA's consideration of an individual's representative payee status under these provisions. The purpose of this matching program is to assist SSA in enforcing all of the above-referenced provisions of the Act.

C. Authority for Conducting the Matching Program

This matching program is carried out under the authority of sections 202(x)(1), 202(x)(3), 205(j)(1)(A), 205(j)(5), 1611(e)(1)(A), 1631(a)(2)(A)(iii) and 1631 (a)(2)(E) of the Social Security Act.

D. Categories of Records and Individuals Covered by the Match

The Federal Bureau of Prisons will submit names and other identifying information of prisoners from its prisoner data systems. The SSA Master Files of Social Security number (SSN) holders and SSN applications contain the SSNs and identifying information for all SSN holders and applicants. The SSA Master Beneficiary Record and Supplemental Security Income contain title II and title XVI beneficiary and payment information. The Master Representative Payee File contains representative payee information. SSA will match data from these record systems with BOP data as a first step in detecting certain individuals who should not be receiving Social Security or SSI benefits, either for themselves, or on behalf of others.

E. Inclusive Dates of the Match

This matching program shall become effective no sooner than 40 days after notice of the program is sent to Congress and the Office of Management and Budget, or 30 days after publication of this notice in the **Federal Register**, whichever date is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 99–21524 Filed 8–18–99; 8:45 am]

BILLING CODE 4190–29–P

SOCIAL SECURITY ADMINISTRATION

Privacy Act of 1974, as amended; Computer Matching Program (SSA/Railroad Retirement Board (RRB)—SSA Match Number 1006)

AGENCY: Social Security Administration (SSA).

ACTION: Notice of computer matching program.

SUMMARY: In accordance with the provisions of the Privacy Act, this notice announces a computer matching program that SSA plans to conduct with RRB.

DATES: SSA will file a report of the subject matching program with the Committee on Governmental Affairs of the Senate, the Committee on Government Reform and Oversight of the House of Representatives and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). The matching program will be effective as indicated below.

ADDRESSES: Interested parties may comment on this notice by either telefax to (410) 597–0841, or writing to the Associate Commissioner for Program Support, 4400 West High Rise Building, 6401 Security Boulevard, Baltimore, MD 21235–6401. All comments received will be available for public inspection at this address.

FOR FURTHER INFORMATION CONTACT: The Associate Commissioner for Program Support as shown above.

SUPPLEMENTARY INFORMATION:

A. General

The Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100–503) amended the Privacy Act (5 U.S.C. 552a) by establishing conditions under which computer matching involving the Federal government could be performed and adding certain protections for individuals applying for and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508), further amended the Privacy Act regarding protections for such individuals. The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. Among other things, it requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain Data Integrity Board approval of the match agreements;

(3) Furnish detailed reports about matching programs to Congress and OMB;

(4) Notify applicants and beneficiaries that their records are subject to matching; and

(5) Verify match findings before reducing, suspending, terminating, or denying an individual's benefits or payments.

B. SSA Computer Matches Subject to the Privacy Act

We have taken action to ensure that all of SSA's computer matching programs comply with the requirements of the Privacy Act, as amended.

Dated: August 12, 1999.

Susan M. Daniels, Ph.D.,

Deputy Commissioner for Disability and Income Security Programs.

Notice of Computer Matching Program, Railroad Retirement Board (RRB) With Social Security Administration (SSA)

A. Participating Agencies

SSA and RRB.

B. Purpose of the Matching Program

To identify supplemental security income recipients and applicants who receive annuities payable by the RRB. For such individuals, the income received due to benefits payable by the RRB may affect eligibility for or the amount of SSI benefits.

C. Authority for Conducting the Matching Program

Sections 1631(e)(1)(B) and 1631(f) of the Social Security Act (42 U.S.C. 1383(e)(1)(B) and 1383(f)).

D. Categories of Records and Individuals Covered by the Match

The RRB will provide SSA with an electronic data file containing annuity payment information from its system of records entitled Checkwriting Integrated Computer Operation Benefits Payment Master. SSA will then match the RRB data with information maintained in its Supplemental Security Income Record.

E. Inclusive Dates of the Match

The matching program shall become effective no sooner than 40 days after notice of the matching program is sent to Congress and the Office of Management and Budget (OMB), or 30 days after publication of this notice in the **Federal Register**, whichever date is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 99–21653 Filed 8–18–99; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–57 (Sub-No. 48X)]

Soo Line Railroad Company—Abandonment Exemption—in Marshall and Roberts Counties, SD

On July 30, 1999, Soo Line Railroad Company, doing business as Canadian Pacific Railway (Soo), filed with the Surface Transportation Board (Board) a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to abandon a line of railroad extending from milepost 208.8± near Rosholt to the end of the line at milepost 236.3± near Veblen, a distance of approximately 27.5 miles in Marshall and Roberts Counties, SD. The line traverses U.S. Postal Service Zip Codes 57224, 57255, 57260, and 57270 and includes the stations of Veblen (milepost 236.3), Claire City (milepost 227.3), Hammer (milepost 223.4), New Effington (milepost 218.3), and Victor (milepost 213.8).

The line does not contain federally granted rights-of-way. Any documentation in the railroad's possession will be made available promptly to those requesting it.

The interest of railroad employees will be protected by *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by November 17, 1999.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each OFA must be accompanied by the filing fee, which currently is set at $1,000. *See* 49 CFR 1002.2(f)(25).

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 CFR 1152.28 or for trail use/rail banking under 49 CFR 1152.29 will be due no later than September 8, 1999. Each trail use request must be accompanied by a $150 filing fee. *See* 49 CFR 1002.2(f)(27).

All filings in response to this notice must refer to STB Docket No. AB–57 (Sub-No. 48X) and must be sent to: (1) Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW, Washington, DC 20423–0001; and (2) Diane P. Gerth, 150 South Fifth Street, Suite 2300, Minneapolis, MN 55402. Replies to the Soo petition are due on or before September 8, 1999.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Services at (202) 565–1592 or refer to the full abandonment or discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis (SEA) at (202) 565–1545. [TDD for the hearing impaired is available at (202) 565–1695.]

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by SEA will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Other interested persons may contact SEA to obtain a copy of the EA (or EIS). EAs in these abandonment proceedings normally will be made available within 60 days of the filing of the petition. The deadline for submission of comments on the EA will generally be within 30 days of its service.

Board decisions and notices are available on our website at ''WWW.STB.DOT.GOV.''

Decided: August 11, 1999.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 99–21445 Filed 8–18–99; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

August 13, 1999.

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, Public Law 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.

DATES: Written comments should be received on or before September 20, 1999 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–0158.

Form Number: IRS Form 3206.

Type of Review: Extension.

Title: Information Statement by United Kingdom Withholding Agents Paying Dividends From U.S. Corporations to Resident of the United States and Certain Treaty Countries.

Description: Form 3206 is used to report dividends paid by U.S. corporations through United Kingdom nominees to beneficial owners who are residents of countries other than the United Kingdom with which the U.S.

has a tax treaty providing for reduced withholding rates on dividends. The data is used by IRS to determine whether the proper amount of income tax was withheld.

Respondents: Business or other for-profit, Individuals and households.

Estimated Number of Respondents/ Recordkeepers: 5,000.

Estimated Burden Hours Per Respondent/Recordkeeper: 4 hr., 6 min.

Frequency of Response: On occasion.

Estimated Total Reporting/ Recordkeeping Burden: 15,620 hours.

OMB Number: 1545–0941.

Form Number: IRS Form 8308.

Type of Review: Extension.

Title: Report of a Sale or Exchange of Certain Partnership Interests.

Description: Form 8308 is an information return that gives the IRS the names of the parties involved in a section 751(a) exchange of a partnership interest. It is also used by the partnership as a statement to the transferor or transferee. It alerts the transferor that a portion of the gain on the sale of a partnership interest may be ordinary income.

Respondents: Business or other for-profit, Individuals or households, Farms.

Estimated Number of Respondents/ Recordkeepers: 200,000.

Estimated Burden Hours Per Respondent/Recordkeeper:

Recordkeeping—2 hr., 23 min.
Learning about the law or the form—2 hr., 23 min.
Preparing and sending the form to the IRS—2 hr., 32 min.

Frequency of Response: On occasion.

Estimated Total Reporting/ Recordkeeping Burden: 1,460,000 hours.

OMB Number: 1545–1004.

Form Number: IRS Form 1120–REIT.

Type of Review: Extension.

Title: U.S. Income Tax Return for Real Estate Investment Trusts (REIT)

Description: Form 1120–REIT is filed by a corporation, trust, or association electing to be taxed as a REIT in order to report its income, and deductions, and to compute its tax liability. IRS uses Form 1120–REIT to determine whether the REIT has correctly reported its income, deductions, and tax liability.

Respondents: Business or other for-profit.

Estimated Number of Respondents/ Recordkeepers: 363.

Estimated Burden Hours Per Respondent/Recordkeeper:

Recordkeeping—60 hr., 2 min.
Learning about the law or the form—21 hr., 36 min.
Preparing the form—41 hr., 12 min.
Copying, assembling, and sending the form to the IRS—5 hr., 5 min.

Frequency of Response: Annually.

Estimated Total Reporting/ Recordkeeping Burden: 46,435 hours.

OMB Number: 1545–1012.

Form Number: IRS Form 5305A–SEP.

Type of Review: Extension.

Title: Salary Reduction and Other Elective Simplified Employee Pension—Individual Retirement Accounts Contribution Agreement.

Description: Form 5305A–SEP is used by an employer to make an agreement to provide benefits to all employees under a salary reduction Simplified Employee Pension (SEP) described in section 408(k). This form is not to be filed with IRS, but is to be retained in the employers' records as proof of establishing such a plan, thereby justifying a deduction for contributions made to the SEP. The data is used to verify the deduction.

Respondents: Business or other for-profit.

Estimated Number of Respondents/ Recordkeepers: 100,000.

Estimated Burden Hours Per Respondent/Recordkeeper:

Recordkeeping—4 hr., 29 min.
Learning about the law or the form—5 hr., 1 min.
Preparing the form—58 min.

Frequency of Response: On occasion.

Estimated Total Reporting/ Recordkeeping Burden: 1,046,000 hours.

OMB Number: 1545–1411.

Form Number: IRS Forms 8843.

Type of Review: Extension.

Title: Statement for Exempt Individuals and Individuals With a Medical Condition.

Description: Form 8843 is used by an alien individual to explain the basis of the individual's claim that he or she is able to exclude days of presence in the U.S. because the individual is a teacher/trainee or student; professional athlete; or has a medical condition or problem.

Respondents: Individuals and households.

Estimated Number of Respondents/ Recordkeepers: 150,000.

Estimated Burden Hours Per Respondent/Recordkeeper:

	Form 8843, parts I and II	Form 8843, parts I and III	Form 8843, parts I and IV	Form 8843, parts I and V
Recordkeeping	13 min	13 min	13 min	13 min.
Learning about the law or the form	7 min	7 min	6 min	7 min
Preparing the form	31 min	34 min	25 min	29 min.
Copying, assembling, and sending the form to the IRS.	17 min	17 min	17 min	17 min.

Frequency of Response: Annually.

Estimated Total Reporting/ Recordkeeping Burden: 177,120 hours.

OMB Number: 1545–1424.

Form Number: IRS Form 1099–C.

Type of Review: Extension.

Title: Cancellation of Debt.

Description: Form 1099–C is used for reporting canceled debt, as required by section 6050P of the Internal Revenue Code. It is used to verify that debtors are correctly reporting their income.

Respondents: Business or other for-profit, Not-for-profit institutions, Federal Government.

Estimated Number of Respondents: 647,993.

Estimated Burden Hours Per Respondent: 10 minutes.

Frequency of Response: Annually.

Estimated Total Reporting Burden: 110,159 hours.

OMB Number: 1545–1498.

Regulation Project Number: REG–209826–96 NPRM.

Type of Review: Extension.

Title: Application of the Grantor Trust Rules to Nonexempt Employees' Trust.

Description: The regulations provide rules for the application of the grantor trust rules to certain nonexempt employees' trusts. Taxpayers must indicate on a return that they are relying on a special rule to reduce the overfunded amount of the trust.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 1,000.

Estimated Burden Hours Per Respondent: 1 hour.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 1,000 hours.

OMB Number: 1545–1653.

Revenue Procedure Number: Revenue Procedure 99–26.

Type of Review: Extension.

Title: Secured Employee Benefits Settlement Initiative.

Description: This revenue procedure provides taxpayers options to settle cases in which they accelerated deductions for accrued employee benefits secured by a letter of credit, bond, or other similar financial instrument.

Respondents: Business or other for-profit.

Estimated Number of Respondents/Recordkeepers: 100.

Estimated Burden Hours Per Respondent/Recordkeeper: 20 hours.

Frequency of Response: Other (one-time).

Estimated Total Reporting/Recordkeeping Burden: 2,000 hours.

Clearance Officer: Garrick Shear, 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 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 99–21550 Filed 8–18–99; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of Citizen Advocacy Panel, Midwest District

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: An open meeting of the Midwest Citizen Advocacy Panel will be held in Omaha, Nebraska.

DATES: The meeting will be held Thursday, September 16, 1999 and Friday, September 17, 1999.

FOR FURTHER INFORMATION CONTACT: Sandra McQuin at 1–888–912–1227, or 414–297–1604.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Citizen Advocacy Panel (CAP) will be held Thursday, September 16, 1999, from 1:00 to 5:00 p.m. at the Ramada Inn Central, 7007 Grover Street, Omaha, NE 68106 and 7:00 p.m. to 9:00 p.m. at the Best Western Central Executive Center, 3650 S. 72nd Street, Omaha, NE 68124 and Friday, September 17, 1999, from 9:00 a.m. to 3:00 p.m. at the Ramada Inn Central, 7007 Grover Street, Omaha, NE 68106. The Citizen Advocacy Panel is soliciting public comment, ideas, and suggestions on improving customer service at the Internal Revenue Service. The public is invited to make oral comments on Thursday September 16, 1999, 7:00 p.m. to 9:00 p.m.; written comments will be read into the record. Individual comments will be limited to five minutes and an additional five minutes allotted for questions and answers. If you would like to have the CAP consider a written statement or pre-register to make an oral comment, please call the CAP office at 1–888–912–1227 or 414–297–1604, FAX (414) 297–1623, or mail to Citizen Advocacy Panel, Mail Stop 1006–MIL, 310 W. Wisconsin Ave, Milwaukee, Wisconsin 53203–2221. If you would like to pre-register for the meeting, the only information needed by the CAP office is number of attendees and zip code. The Agenda will include the following: Reports by the CAP sub-groups, presentation of taxpayer issues by individual members, CAP office report, and discussion of issues.

Note: Last minute changes to the agenda are possible and could prevent effective advance notice.

Dated: August 13, 1999.

Wendy S. Handin,

CAP Project Manager, Acting.

[FR Doc. 99–21501 Filed 8–18–99; 8:45 am]

BILLING CODE 4830–01–P

UNITED STATES INFORMATION AGENCY

Culturally Significant Objects Imported for Exhibition Determination: ''Kremlin Gold—1000 Years of Russian Gems & Jewels''

AGENCY: United States Information Agency.

ACTION: Notice.

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978 (43 FR 13359, March 29, 1978), and Delegation Order No. 85–5 of June 27, 1985 (50 FR 27393, July 2, 1985), I hereby determine that the objects to be included in the exhibit, ''Kremlin Gold—1000 Years of Russian Gems & Jewels'' imported from abroad for the temporary exhibition without profit within the United States, are of cultural significance. These objects are imported pursuant to a loan agreement with the foreign lender. I also determine that the exhibition or display of the listed objects at the Houston Museum of Natural Science, Houston, TX, from on or about April 15, 2000, to on or about September 4, 2000, and the Field Museum of Natural History in Chicago, Chicago, IL, from on or about October 4, 2000, to on or about January 15, 2001, is in the national interest. Public Notice of these determinations is ordered to be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For a copy of the list of exhibit objects and for further information, contact Ms. Neila Sheahan, Assistant General Counsel, Office of the General Counsel, 202/619–5030. The address is Room 700, U.S. Information Agency, 301 4th Street, SW, Washington, DC 20547–0001.

Dated: August 11, 1999.

Les Jin,

General Counsel.

[FR Doc. 99–21536 Filed 8–18–99; 8:45 am]

BILLING CODE 8230–01–M

federal register

Thursday
August 19, 1999

Part II

Department of Health and Human Services

Administration for Children and Families

Request for Applications for the Office of Community Services' Fiscal Year 2000 Discretionary Grants Program; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. OCS–2000–01]

Program Announcement; Request for Applications for the Office of Community Services' Fiscal Year 2000 Discretionary Grants Program

AGENCY: Office of Community Services, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for applications for the Office of Community Services' Fiscal Year 2000 Discretionary Grants Program.

SUMMARY: The Administration for Children and Families (ACF), Office of Community Services (OCS), announces that competing applications will be accepted for new grants pursuant to the Secretary's discretionary authority under sections 681(a) and (b) of the Community Services Block Grant Act of 1981, as amended.

CLOSING DATE: The closing date for submission of applications is November 15, 1999. Mailed applications postmarked after the closing date will be classified as late.

APPLICATION SUBMISSION:

Mailing Address: Discretionary applications must be mailed to the U.S. Department of Health and Human Services, Administration for Children and Families, Office of Grants Management/OCSE, 4th Floor West, Aerospace Center, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447; Attention: Discretionary Grants Program.

Submission Instructions: Mailed applications shall be considered as meeting an announced deadline if they are either received on or before the closing date or postmarked on or before the closing date and received by ACF in time for the independent review.

Applications mailed must bear a legibly dated U.S. Postal Service postmark or a legibly dated, machine produced postmark of a commercial mail service affixed to the envelope/package containing the application(s). To be deemed acceptable as proof of timely mailing, a postmark from a commercial mail service must include the logo/emblem of the commercial mail service company and must reflect the date the package was received by the commercial mail service company from the applicant. Private metered postmarks shall not be acceptable as proof of timely mailing. (Applicants are cautioned that express/overnight mail services do not always deliver as agreed.)

Applications handcarried by applicants, applicant couriers, or by other representatives of the applicant shall be considered as meeting an announced deadline if they are received on or before the closing date, between the hours of 8:00 a.m. and 4:30 p.m., EST, at the U.S. Department of Health and Human Services, Administration for Children and Families, Office of Grants Management/OCSE, ACF Mailroom, 2nd Floor Loading Dock, Aerospace Center, 901 D Street, S.W., Washington, D.C. 20024, between Monday and Friday (excluding Federal holidays). The address must appear on the envelope/package containing the application with the note Attention: Discretionary Grants Program. (Applicants are again cautioned that express/overnight mail services do not always deliver as agreed.)

ACF cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ACF electronically will not be accepted regardless of date or time of submission and time of receipt.

Late applications: Applications that do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

Extension of deadlines: ACF may extend application deadlines when circumstances such as acts of God (floods, hurricanes, etc.) occur, or when there are widespread disruptions of the mail service. Determinations to extend or waive deadline requirements rest with ACF's Chief Grants Management Officer.

Number of Copies Required: One signed original application and four copies must be submitted at the time of the initial submission. (OMB–0970–0062, expires 10/31/2001)

The first page of the SF–424 must contain in the lower right-hand corner, a designation indicating under which sub-priority area funds are being requested (for example UR for 1.1, HB for 1.2, PD for 1.3, DD for 1.4, AM for 1.5, UT for 1.6, or RF for 2.0). See Part G, section 1, item 11 for details.

For General Questions on the Announcement, Contact:

Veronica Terrell—(202) 401–5295
David Matthews—(202) 401–5271
Walter Thaxton—(202) 401–5269
Bobby Malone—(202) 401–5270
Calvin Brockington—(202) 401–5273
Debra Brown—(202) 401–3446
Thelma Woodland—(202) 401–5294
Ruth Walston—(202) 401–9340

For a Copy of the Announcement, Contact: Administration for Children and Families, Office of Community Services, 370 L'Enfant Promenade, S.W., 5th Floor West, Washington, DC 20447, (202) 401–9345, (202) 401–9354, (202) 401–4687 (fax).

In addition, the announcement will be accessible on the OCS website for reading or downloading at: http://www.acf.dhhs.gov/programs/ocs/kits1.htm.

The Catalog of Federal Domestic Assistance number for this program is 93.570. The title is Community Services Block Grant—Discretionary Awards.

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Part A—Preamble

1. Legislative Authority

The Community Services Block Grant Act of 1981, as amended, (Section 680 of the Coats Human Services Reauthorization Act of 1998), authorizes the Secretary to make funds available to support program activities of national or regional significance to alleviate the causes of poverty in distressed communities with special emphasis on community and economic development activities.

2. Departmental Goals

This announcement is particularly relevant to the Departmental goal of strengthening the American family and promoting self-sufficiency. These programs have objectives of increasing the access of low-income people to employment and business development opportunities, and improving the integration, coordination, and continuity of the various HHS (and other federal Departments') funded services potentially available to families living in poverty.

3. Definitions of Terms

For purposes of this Program Announcement, the following definitions apply:

—*Budget period:* The interval of time into which a grant period of assistance is divided for budgetary and funding purposes.

—*Cash contributions:* The cash outlay that includes the money contributed to the project or program by the recipient and third parties.

—*Community development corporation (CDC):* A private, nonprofit entity, governed by a board of directors consisting of low-income residents of the community and business and civic leaders, that has as a principal purpose planning, developing, or managing low-income housing or community development projects.

—*Community economic development (CED):* A process by which a community uses resources to attract capital and increase physical, commercial, and business development and job opportunities for its residents.

—*Construction projects:* For the purpose of this announcement, construction projects involve land improvements and development or major renovation of (new or existing) facilities and buildings, including their improvements, fixtures and permanent attachments.

—*Displaced worker:* An individual who is in the labor market but has been unemployed for six months or longer.

—*Distressed community:* A geographic urban neighborhood or rural community of high unemployment and pervasive poverty.

—*Eligible applicant:* (See appropriate Program Priority Area under Part C.)

—*Employment education and training program:* A program that provides education and/or training to welfare recipients, at-risk youth, public housing tenants, displaced workers, homeless and low-income individuals and that has demonstrated organizational experience in education and training for these populations.

—*Empowerment Zones and Enterprise Communities (EZ/EC):* Those communities designated as such by the Secretaries of Agriculture or Housing and Urban Development.

—*Equity investment:* The provision of capital to a business entity for some specified purpose in return for a portion of ownership using a third party agreement as the contractual instrument.

—*Indian tribe:* A tribe, band, or other organized group of Indians recognized in the State in which it resides or which is considered by the Secretary of the Interior to be an Indian tribe or an Indian organization for any purpose. For the purpose of Priority Area 1.0 (Urban and Rural Community Economic Development), an Indian tribe or Indian organization is ineligible unless the applicant organization is a private non-profit community economic development corporation.

—*Job creation:* New jobs, *i.e.* jobs not in existence prior to the start of the project, that result from new business startups, business expansion, development of new services industries, and/or other newly-undertaken physical or commercial activities.

—*Job placement:* Placing a person in an existing vacant job of a business, service, or commercial activity not related to new development or expansion activity.

—*Letter of commitment:* A signed letter or agreement from a third party to the applicant that pledges financial or other support for the grant activities only subject to receiving an award of OCS grant funds.

—*Loan:* Money lent to a borrower under a binding pledge for a given purpose to be repaid, usually at a stated rate of interest and within a specified period of time.

—*Poverty Income Guidelines:* Guidelines published annually by the U.S. Department of Health and Human Services that establish the level of poverty defined as low-income for individuals and their families.

—*Program income:* Gross income earned by the grant recipient that is directly generated by an activity supported with grant funds.

—*Project period:* The total time for which a project is approved for OCS support, including any approved extensions.

—*Revolving loan fund:* A capital fund established to make loans whereby repayments are re-lent to other borrowers.

—*Self-employment:* The state of an individual or individuals who engage in self-directed economic activities.

—*Self-sufficiency:* The economic state not requiring public assistance for an individual and his (her) immediate family.

—*Subaward:* An award of financial assistance in the form of money, or property in lieu of money, made under an award by a recipient to an eligible subrecipient or by a subrecipient to a lower tier subrecipient. The term includes financial assistance when provided by any legal agreement, even if the agreement is called a contract, but does not include procurement of goods and services nor does it include any form of assistance which is excluded from the definition of ''award'' in 45 CFR 74.2. (Note: Subawards do not include equity investments or loan transactions since they are promulgated under third party agreements.)

—*Technical assistance:* A problem-solving event generally utilizing the services of an expert. Such services may be provided on-site, by telephone, or by other communications. These services address specific problems and are intended to assist with the immediate resolution of a given problem or set of problems.

—*Temporary Assistance to Needy Families (TANF):* Title I of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Pub.L. 104–193) creates the TANF program that transforms welfare into a system that requires work in exchange for time-limited assistance. The law specifically eliminates any individual entitlement to or guarantee of assistance, repeals the Aid to Families with Dependent Children (AFDC) program, Emergency Assistance (EA) and Job Opportunities and Basic Skills Training (JOBS) programs, and replaces them with a Block grant entitlement to States under Title IV of the Social Security Act.

—*Third party:* Any individual, organization, or business entity that is not the direct recipient of grant funds.

—*Third party agreement:* A written agreement entered into by the grantee and an organization, individual or business entity (including a wholly-owned subsidiary), by which the grantee makes an equity investment or a loan in support of grant purposes.

—*Third party in-kind contributions:* The value of non-cash contributions provided by non-federal third parties which may be in the form of real property, equipment, supplies and other expendable property, and the value of goods and services directly benefitting and specifically identifiable to the project or program.

Part B—Application Prerequisites

1. Eligible Applicants

Priority areas included in this Program Announcement have differing eligibility requirements. Therefore, eligible applicants are identified in the individual priority area descriptions found in Part C.

2. Availability of Funds

a. Appropriation Amounts

All grant awards are subject to the availability of appropriated funds. Approximately $26,560,000 is expected to be available for FY 2000. The approximate amount of funds anticipated to be available for each priority area is summarized below:

Sub-priority areas	FY 2000 funds
PRIORITY AREA 1.0: URBAN AND RURAL COMMUNITY ECONOMIC DEVELOPMENT	
1.1 Urban and Rural Community Economic Development (Operational)	17,000,000
1.2 Urban and Rural Community Economic Development (HBCU Set-Aside)	2,100,000
1.3 Urban and Rural Community Economic Development (Pre-Developmental Set-Aside)	750,000
1.4 Urban and Rural Community Economic Development (Developmental Set-Aside)	2,500,000
1.5 Administrative and Management Expertise (Set Aside)	500,000
1.6 Training and Technical Assistance (Set Aside)	210,000
PRIORITY AREA 2.0: RURAL COMMUNITY DEVELOPMENT ACTIVITIES	
2.0 Rural Community Facilities Development (Water and Waste Water Treatment Systems Development)	3,500,000

b. Grant Amounts

The approximate amounts to be granted for projects under the sub-priority areas are indicated below:

Sub-priority area	Funding limit
1.1	Approximately 13 at $350,000 but not more than $500,000
	Approximately 30 at $349,999 or less
1.2	Approximately 6 at $350,000
1.3	Approximately 10 at $75,000
1.4	Approximately 10 at $250,000
1.5	Approximately 1 at $500,000
1.6	Approximately 1 at $210,000
2.0	Approximately 8 from $300,000–$533,000

3. Project and Budget Periods

For Sub-Priority Areas 1.1, 1.2, and 1.4, applicants with projects involving construction only, may request a project period of up to 60 months and a budget period of up to 36 months. Applicants for non-construction projects under these priority areas may request project periods of up to 36 months and budget periods of up to 17 months. Applicants for Sub-Priority Areas 1.5 and 1.6 may request project and budget periods of up to 17 months. For Sub-Priority Area 1.3, applicants may request project and budget periods of up to 12 months.

For Priority Area 2.0, grantees will be funded for 24 month project periods and 12 month budget periods.

4. Mobilization of Resources

OCS encourages and strongly supports leveraging of resources through public/private partnerships which can mobilize cash and/or third-party in-kind contributions.

5. Program Beneficiaries

Projects proposed for funding under this Announcement must result in direct benefits to low-income people as defined in the most recent annual revision of the Poverty Income Guidelines published by DHHS.

Attachment A of the appendices to this Announcement is an excerpt from the Poverty Income Guidelines currently in effect. Annual revisions of these guidelines are normally published in the **Federal Register** in February or early March of each year. Grantees will be required to apply the most recent guidelines throughout the project period. These revised guidelines may be obtained at public libraries, Congressional offices, or by writing the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, D.C. 20402. Also, see ''For General Questions On the Announcement Contact'' at the beginning of this Announcement.

No other government agency or privately-defined poverty guidelines are applicable for the determination of low-income eligibility for these OCS programs.

Note, however, that low-income individuals granted lawful temporary resident status under Sections 245A or 210A of the Immigration and Nationality Act, as amended by the Immigration Reform and Control Act of 1986 (Public law 99–603), may not be eligible for direct or indirect assistance based on financial need under this program for a period of five years from the date such status was granted.

6. Number of Projects in Application

All Priority Area 1.0 applications may contain only one project except for Sub-Priority Areas 1.3, 1.5, and 1.6 where applicants are researching various opportunities, are sharing administrative and management expertise with current OCS grantees, or are providing training and/or technical assistance for current OCS grantees, including the organization of seminars and other activities in assisting community development corporations. Applications that are not in compliance with this requirement may be disqualified.

7. Multiple Submittals

There is no limit to the number of applications that can be submitted under a specific program priority area as long as each application contains a proposal for a different project. However, an applicant can receive only one grant in each priority area. Also, applicants who receive more than one grant for a common budget/project period must be mindful that salaries and wages claimed for the same persons cannot collectively exceed 100% of total annual salary.

8. Subawarding Projects

OCS does not fund projects where the role of the applicant is *primarily* to serve as a conduit for funds through the use of subawards to other organizations. In cases where the applicant proposes to make one or more subawards, it must retain a substantive role in the implementation and operation of the project for which funding is requested.

9. Third Party Agreements

Any applicant submitting a proposal for funding under Sub-Priority Areas 1.1, 1.2, or 1.4 who proposes to use some or all of the requested OCS funds to enter into a third party agreement in order to make an equity investment (such as the purchase of stock) or a loan to an organization, or business entity (including a wholly-owned subsidiary), must include in the application, along with the business plan, a copy of the signed third party agreement for approval by OCS.

A third party agreement covering an equity investment must contain, at a minimum, the following:

1. The type of equity transaction (*e.g.* stock purchase).
2. Purpose(s) for which the equity investment is being made.
3. Cost per share.
4. Number of shares being purchased.
5. Percentage of ownership of the business.
6. Number of seats on the board, if applicable.

A third party agreement covering a loan transaction must contain, at a minimum, the following information:

1. Purpose(s) for which the loan is being made.
2. Rates of interest and other fees.
3. Terms of loan.
4. Repayment schedules.
5. Collateral security.
6. Default and collection procedures.

All third party agreements must include written commitments as follows:

From the third party (as appropriate):

1. A minimum of 75% of the jobs to be created as a result of the injection of grant funds will be filled by low-income individuals.
2. The grantee will have the right to screen applicants for jobs to be filled by low-income individuals and to verify their eligibility.
3. If the grantee's equity investment equals 25% or more of the business's assets, the grantee will have representation on the board of directors.
4. Reports will be made to the grantee regarding the use of grant funds no less than on a quarterly basis.
5. A procedure will be developed to assure that there are no duplicate counts of jobs created.
6. Detailed information will be provided on how the grant funds will be used by the third party by submitting a Source and Use of Funds Statement. In addition, the agreement must provide details on how the grantee will provide support and technical assistance to the third party in areas of recruitment and retention of low-income individuals.

From the grantee:

Detailed information on how the grantee will provide support and technical assistance to the third party in areas of recruitment and retention of low-income individuals.

All third party agreements should be accompanied by:

1. A signed statement from a Certified or Licensed Public Accountant as to the sufficiency of the third party's financial management system in accordance with 45 CFR 74, to protect adequately any federal funds awarded under the application.
2. Financial statements for the third party organization for the prior three years. (If not available because the organization is a newly-formed entity, include a statement to this effect.)
3. The third party agreement will specify how the grantee will provide oversight of the third party for the life of the agreement. Also, the agreement will specify that the third party will maintain documentation related to the grant objectives as specified in the agreement and will provide the grantee and HHS access to that documentation.

If a signed third party agreement is not available when the application is submitted, the applicant must submit as part of the narrative as much of the above-mentioned information as possible in order to enable reviewers to evaluate the proposal. It should be noted that portion of a grant which will be used to fund a third party agreement will not be released until the agreement has been approved by OCS.

10. Funding Considerations

In cases where an application ranks highly and is competitive, the following may apply:

1. When the applicant is proposing to enter into a third party agreement for all of the grant's operational funds, OCS will send a time-limited letter of intent to fund pending receipt of a signed third party agreement. Once OCS has determined that the agreement is acceptable, an award will be forwarded to the applicant.
2. Previous performance of applicants will be considered an important determining factor in the grant award decisions.
3. Any applicant that has three or more active OCS grants may only be funded under exceptional circumstances.
4. Pre-award site visits may be performed for the purpose of undertaking assessments of many of these applications prior to OCS making final determinations on grant awards.
5. OCS will consider applications that include revolving loan funds as a grant activity.

11. Prohibited Activities

OCS will not consider applications that propose the establishment of Small Business Investment Corporations or Minority Enterprise Small Business Investment Corporations.

Part C—Program Priority Areas

The program priority areas of the Office of Community Services' Discretionary Grants Program are as follows:

Priority Area 1.0 Urban and Rural Community Economic Development

Sub-Priority Areas Under 1.0

1.1 Urban and Rural Community Economic Development (Operational)
1.2 Urban and Rural Community Economic Development (HBCU Set-Aside)
1.3 Urban and Rural Community Economic Development (Pre-Developmental Set-Aside)

1.4 Urban and Rural Community Economic Development (Developmental Set-Aside)
1.5 Administrative and Management Expertise (Set-Aside)
1.6 Training and Technical Assistance (Set-Aside)

Priority Area 2.0 Rural Community Facilities Development (Water and Waste Water Treatment Systems Development)

Priority Area 1.0 Urban and Rural Community Economic Development

Eligible applicants are private, non-profit community development corporations (CDCs) governed by a board consisting of residents of the community and business and civic leaders that has as a principal purpose planning, developing, or managing low-income housing or community development projects.

The purpose of this priority area is to encourage the creation of projects intended to provide employment and business development opportunities for low-income people through business, physical or commercial development. Generally the opportunities must aim to improve the quality of the economic and social environment of TANF recipients; low-income residents including displaced workers; at-risk teenagers; non-custodial parents, particularly those of children receiving TANF assistance; individuals residing in public housing; individuals who are homeless; and those with developmental disabilities. Grant funds under this sub-priority area are intended to provide resources to eligible applicants (CDCs) but also have the broader objectives of arresting tendencies toward dependency, chronic unemployment, and community deterioration in urban and rural areas.

Sub-Priority Area 1.5 is intended to provide administrative and management expertise to current Office of Community Services' grantees who are experiencing problems in the implementation of urban and rural community economic development projects.

Sub-Priority Area 1.6 provides funds for providing training and technical assistance to groups of community development corporations in developing or implementing projects funded under this section and its aim is to generally enhance the viability and competence of community development corporations.

This Priority Area also seeks to attract additional private capital into distressed communities, including empowerment zones and enterprise communities, and to build and/or expand the ability of local institutions to better serve the economic needs of local residents.

Applicant must submit proof of non-profit status in its application at the time of submission. The non-profit agency can accomplish this by providing a copy of the applicants listing in the Internal Revenue's Service's (IRS) most recent list of tax-exempt organizations described in Section 501 (C)(3) of the IRS tax code. Applications that do not include proof of this status will be disqualified.

Sub-Priority Area 1.1 Urban and Rural Community Economic Development (Operational)

Funds will be provided to a limited number of private non-profit community development corporations for business development activities at the local level. Funding will be provided for specific projects and will require the submission of business plans or work plans, where applicable, that meet the test of economic feasibility. Attachment K should be used as a guideline for the business plan.

The applicant should select a project in an industry in its region that promotes economic sustainability and self-sufficiency for families in the low-income community. OCS encourages each applicant to describe the project scope that includes the low-income community served, the business activities undertaken, and types of jobs to be created. The business activities should be described by Standard Industrial Codes (SIC) and jobs by occupational classifications. This information is published by the U.S. Department of Commerce in the Statistical Abstract of the United States, 1998, Tables No. 679 and 680. Also, applicants may use the material included in Attachment L to identify industrial areas and occupational classifications.

For Fiscal Year 2000, it is anticipated that approximately 30 grants up to a maximum of $349,999 will be awarded and approximately 13 grants of $350,000 but not more than $500,000 will be made. Competition for these funds will be restricted to either the $349,999 and under category or the $350,000 up to $500,000 category. Applications will compete within the category in which they fall.

Projects must further the Departmental goals of strengthening American families and promoting their self-sufficiency. OCS is particularly interested in receiving applications that involve public-private partnerships that are directed toward the development of economic self-sufficiency in distressed communities through projects that focus on providing employment and business development opportunities for low-income people through business startups, business expansions, development of new services industries, and/or other newly-undertaken physical and commercial activities.

Eligible organizations located in Empowerment Zones and Enterprise Communities are urged to submit applications. Likewise, applicants are encouraged to foster partnerships with child support enforcement agencies to increase the capability of low-income non-custodial parents, particularly those of children receiving TANF assistance, to fulfill their parental responsibilities. Such applicants may request funds for a business development project or a project that demonstrates innovative ways to create jobs for low-income persons in the targeted group or community.

Applicants must show that the proposed project:

(1) Creates full-time permanent jobs except where an applicant demonstrates that a permanent part-time job produces actual wages that exceed the HHS poverty guidelines. Seventy-five percent (75%) of the jobs created must be filled by low-income residents of the community and must also provide for career development opportunities. Project emphasis should be on employment of individuals who are unemployed or on public assistance, with particular emphasis on those that are at-risk teenagers, TANF recipients, low-income noncustodial parents (particularly those of children receiving TANF assistance), individuals residing in public housing, and individuals who are homeless. While projected employment in future years may be included in the application, it is essential that the focus of employment projects concentrates on those permanent jobs created during the duration of the OCS project period; and/or

(2) Creates a significant number of business development opportunities for low-income residents of the community or significantly aids such residents in maintaining economically viable businesses; and

(3) Assists low-income participants to become self-sufficient.

In the evaluation process, favorable consideration will be given to applicants under this priority area who show the lowest cost-per-job created. Unless there are extenuating circumstances, OCS will not fund projects where the cost-per-job in OCS funds exceeds $15,000.

In addition, favorable consideration in the evaluation process will be given to applicants who demonstrate their intention to coordinate services with the

local TANF offices and/or other employment education and training offices and child support enforcement agencies that serve the proposed area. The offices and agencies should serve welfare recipients, at-risk youth, public housing tenants, displaced workers, homeless and low-income individuals (as defined by the annual revision to the Poverty Income Guidelines published by DHHS) including non-custodial parents. Applicants should submit a written agreement from the applicable office or agency that indicates what actions will be taken to integrate/coordinate services that relate directly to the project for which funds are being requested. The agreement should include the goals and objectives (including target groups) that the applicant and the employment education and training office and child support enforcement agencies expect to reach through their collaboration. It should describe the cooperative relationship, including specific activities and/or actions each of these entities proposes to carry out in support of the project, and the mechanism(s) to be used in coordinating those activities if the project is funded by OCS. Documentation that illustrates the organizational experience of the employment education and training office should also be included.

OCS encourages applications that will develop linkages or agreements with local agencies responsible for administering TANF programs and child support enforcement agreements. OCS would expect these programs to create new jobs for TANF recipients and low-income non-custodial parents, particularly those of children receiving TANF assistance. These initiatives can be accomplished through a variety of business development projects funded under this priority area, *i.e.*, business expansions, new business development and self-employment activities, etc.

OCS does not fund education and training programs. In projects where participants must be trained, any funds that are proposed to be used for training purposes must be limited to providing specific job-related training to those individuals who have been selected for employment in the grant supported project which includes new business startups, business expansions, development of new service industries, and/or other newly-undertaken physical and commercial activities.

Projects involving training and placement for existing vacant positions will be disqualified.

Projects that would result in the relocation of a business from one geographic area to another with the possible displacement of employees are discouraged.

Applicants must be aware that projects funded under this priority area must be operational by the end of the project period, *i.e.*, businesses must be in place, and low-income individuals actually employed in those businesses.

Sub-Priority Area 1.2 Urban and Rural Community Economic Development (HBCU Set-Aside)

For Fiscal Year 2000, it is anticipated that a set-aside fund of $2,100,000 will be included under this sub-priority area for eligible applicants who submit proposals for projects that will be carried out in conjunction with Historically Black Colleges and Universities (HBCUs), as defined in Executive Order Number 12876, dated Nov. 1, 1993, through contract or sub-grant. Such projects must conform to the purposes, requirements, and prohibitions applicable to those submitted under Sub-Priority Area 1.1.

These projects should reflect a significant partnership role for the college or university, and the applicant in doing so will be considered to have fulfilled the goals of the evaluation criterion for Public-Private Partnerships and will be granted the maximum number of points in that category. Applications for these set-aside funds that are not funded due to the limited amount of funds available may also be considered competitively within the larger pool of eligible applicants under Sub-Priority Area 1.1. Any funds that are not used under this sub-priority area due to the limited number of highly scored applications will be rolled over into Sub-Priority Area 1.1.

Any funds that are proposed to be used for training purposes must be limited to providing specific job related training to those individuals who have been selected for employment in the grant supported project which includes new business startups, business expansions, development of new service industries, and/or other newly-undertaken physical or commercial activities.

Sub-Priority Area 1.3 Urban and Rural Community Economic Development (Pre-Developmental Set-Aside)

OCS intends in this sub-priority area to provide funds to recently-established private, non-profit community development corporations that propose to undertake economic development activities in distressed communities.

OCS recognizes that there are a number of newly-organized non-profit community development corporations that have identified needs in their communities but have not had the staff or other resources to develop projects to address those needs. This lack of resources also might be affecting their ability to compete for funds, such as those provided under Sub-Priority Area 1.1 (operational grants), since their limited resources would preclude them from developing a comprehensive business plan and/or mobilizing resources.

OCS has an interest in providing support to these new entities in order to enable them to become more firmly established in their communities, thereby bringing technical expertise and new resources to previously unserved or underserved communities. Therefore, OCS is setting aside funds in Fiscal Year 2000 for grants to private, non-profit community development corporations that have never received OCS funding and have been in existence for no more than three years, or have been in existence longer than three years but have no record of participation in economic development type projects. For the latter, a CDC must state that it has not been active. Also, for this sub-priority area only, the phrase ''no participation in economic development-type projects'' means an eligible applicant has not sponsored nor had any significant participation in projects that have provided employment or business development opportunities through business startups, business expansions, development of new service industries, and/or newly-undertaken physical or commercial activities.

In addition, applicants with housing experience must not have had primary responsibility in planning, developing, and managing housing. OCS anticipates that grants of up to $75,000 each will be made to eligible applicants. These grants will be made for a period of one year and will not require leveraged or mobilized funds.

With funding received under this sub-priority area, CDCs may incur costs to: (1) Evaluate the feasibility of potential projects that address identified needs in the low-income community and that conform to those projects and activities allowable under Sub-Priority Areas 1.1, 1.2, and 1.4; (2) develop a business plan related to one of those projects; and (3) mobilize resources to be contributed to one of those projects, including the utilization of HBCUs.

Based on the availability of funds in Fiscal Year 2001, OCS will consider establishing a set-aside in Priority Area 1.4 to provide operational funds to those organizations which received pre-developmental grants. Grants might be for a maximum of $250,000 and competition for those funds would be

restricted to those organizations that received Fiscal Years 1999 and 2000 pre-developmental grants. The business plan developed as a result of the pre-developmental grant would be submitted as part of the competitive application.

Specifically, each application for Fiscal Year 2000 funds under this sub-priority area must include the following as part of the project narrative:

1. Description of the impact area, *i.e.*, a description of the low-income area it proposes to address;
2. Analysis of need in the distressed community;
3. How the potential projects relate to applicant's organizational goals and previous experience (if any);
4. Project design and implementation factors including a discussion of potential projects that might be implemented to address identified needs, a strategy for conduct of feasibility studies on potential projects and quarterly work plans with specific task timelines and a self-evaluation component; and
5. Project objectives and measurable impact, *i.e.*, a discussion of preparing a business plan on only one selected project based on results of the feasibility studies and plan for mobilization of nondiscretionary dollars to implement it.

Applications that are not funded within this set-aside due to the limited amount of funds available may also be considered competitively within the larger pool of eligible applicants. Any funds that are not used under this sub-priority area due to the limited number of highly scored applications will be rolled over into another priority area.

Sub-Priority Area 1.4 Urban and Rural Community Economic Development (Developmental Set-Aside)

OCS intends in this sub-priority area to provide funds to organizations that received grants from OCS in Fiscal Years 1998 and 1999 under Priority Area 1.3, the pre-developmental grant program. These organizations will compete only among themselves. Such projects must conform to the purposes, requirements and prohibitions applicable to those submitted under Sub-Priority Area 1.1. Applications that are not funded within this set-aside due to the limited amount of funds available may also be considered competitively within the larger pool of eligible applicants under Sub-Priority Area 1.1. Any funds that are not used under this sub-priority area due to the limited number of highly scored applications will be rolled over into Sub-Priority Area 1.1.

Sub-Priority Area 1.5 Administrative and Management Expertise (Set-Aside)

OCS believes that one of the most effective means of assuring the successful operation of a project under the Discretionary Grants Program area is through the sharing amongst CDCs of their experiences in dealing with the day-to-day issues and challenges presented in promoting community economic development. Accordingly, OCS strongly encourages more experienced CDCs to share their administrative and management expertise with less experienced CDCs or with those who have encountered difficulties in operationalizing their work programs. In order to facilitate this, OCS will provide funds to one or more community development corporations to assist with their efforts to enhance the management and operational capacities of the less experienced CDCs or those having difficulties.

OCS anticipates that the grant(s) would be for a maximum of $500,000 with project and budget periods not to exceed 17 months.

OCS will share with the grantee(s) information on other grantees seeking to benefit from such assistance. Such formal requests could also be initiated by a grantee with the concurrence of OCS. These contacts may occur on-site, by telephone, or by other methods of communication. Costs incurred in connection with participating in such activities will be borne by the recipient(s) of the OCS grant under this sub-priority area.

Applicants in this sub-priority area are expected to disseminate results of the project via a handbook, a progress paper, evaluation reports, general manual, or seminars/workshops.

Sub-Priority Area 1.6 Training and Technical Assistance (Set-Aside)

Funds will be awarded to one organization under this priority area for the purpose of providing training and technical assistance to strengthen the network of CDCs.

OCS anticipates that the grant will be for $210,000 with a grant period not to exceed 17 months. Applicant must have the ability to collect and analyze data nationally that may benefit CDCs and be able to disseminate information to all OCS-funded grantees; publish a national directory of funding sources for CDCs (public, corporate, foundation, religious); publish research papers on specific aspects of job creation by CDCs; design and provide information on successful projects and economic niches that CDCs can target. The applicant also will be responsible for the development of instructional programs, national conferences, seminars, and other activities to assist community development corporations.

Eligible applicants are private non-profit organizations. Applicants must operate on a national basis and have significant and relevant experience in working with community development corporations.

Priority Area 2.0 Rural Community Facilities Development (Water and Waste Water Treatment Systems Development)

Funds will be provided under this priority area to help low-income rural communities develop the capability and expertise to establish and/or maintain affordable, adequate, and safe water and waste water treatment facilities.

Funds provided under this priority area may not be used for construction of water and waste water treatment systems or for operating subsidies for such systems, but other mobilized funds may be used for these activities. Therefore, it is suggested that applicants coordinate projects with the Farmers Home Administration (FmHA) and other Federal and state agencies to ensure that funds for hardware for local community projects are available.

Eligible applicants are multi-state, regional private non-profit organizations that can provide training and technical assistance to small, rural communities in meeting their community facility needs.

Part D—Criteria for Review and Evaluation of All Applications

1. Criteria for Review and Evaluation of All Applications Submitted Under Sub-Priority Areas 1.1, 1.2, and 1.4

a. Criterion I: Analysis of Need (Maximum: 5 points)

The application documents that the project addresses a vital need in a distressed community. (0–3 points)

Most recent available statistics and other information are provided in support of its contention. (0–2 points)

b. Criterion II: Organizational Experience in Program Area and Staff Responsibilities (Maximum: 25 points)

(1) *Organizational experience in program area (sub-rating: 0–15 points)*

Documentation provided indicates that projects previously undertaken have been relevant and effective and have provided permanent benefits to the low-income population. (0–5 points)

The applicant has demonstrated the ability to implement major activities in such areas as business development,

commercial development, physical development, or financial services; the ability to mobilize dollars from sources such as the private sector (corporations, banks, etc.), foundations, the public sector (including state and local governments) or individuals; that it has a sound organizational structure and proven organizational capability; and an ability to develop and maintain a stable program in terms of business, physical, or community development activities that will provide needed permanent jobs, services, business development opportunities, and other benefits to community residents. (0–10 points)

(2) *Staff skills, resources and responsibilities (sub-rating 0–10 points)*

The application describes in brief resume form the experience and skills of the project director who is not only well qualified, but whose professional capabilities are relevant to the successful implementation of the project. If the key staff person has not yet been identified, the application contains a comprehensive position description that indicates that the responsibilities to be assigned to the project director are relevant to the successful implementation of the project. (0–5 points)

The applicant has adequate facilities and resources (*i.e.* space and equipment) to successfully carry out the work plan. (0–2 points)

The assigned responsibilities of the staff are appropriate to the tasks identified for the project and sufficient time of senior staff will be budgeted to assure timely implementation and cost effective management of the project. (0–3 points)

c. Criterion III: Project Implementation (Maximum: 25 points)

The business plan or work plan, where applicable, is both sound and feasible. Briefly the plan should describe the key work tasks and show how the project objectives will be accomplished including the development of business and creation of jobs for low-income persons during the allowable OCS project period. The project is responsive to the needs identified in the Analysis of Need. (0–5 points)

It sets forth realistic quarterly time targets by which the various work tasks would be completed. (0–5 points)

Critical issues or potential problems that might impact negatively on the project are defined and the project objectives can be reasonably attained despite such potential problems. (0–5 points)

The application contains a full and accurate description of the proposed use of the requested financial assistance.

If the applicant proposes to make an equity investment or a loan to an individual, organization, or business entity (including a wholly-owned subsidiary), the application includes a signed third party agreement; a signed statement by a Certified or Licensed Public Accountant, as to the sufficiency of the third party's financial management system; and financial statements for the third party's prior three years of operation. (If newly formed and unable to provide the information regarding the prior three years of operation, a statement to that effect should be included.) If the applicant states that an agreement is not currently in place, the application must contain in the narrative as much information required for third party agreements as is available. (See Part B, item 9.)

Also, if the project proposes the development of a new or expanding business, service, physical or commercial activity, the application must address applicable elements of a business plan. Guidelines for a Business Plan are included in Attachment K.

Special attention should be given to assure that the financial plan element, which indicates the project's potential and timetable for financial self-sufficiency, is included. It must include for the applicant and the third party, if appropriate, the following exhibits for the first three years (on a quarterly basis) of the business' operations: Profit and Loss Forecasts, Cash Flow Projections, and Proforma Balance Sheets. Based on these documents, the application must also contain an analysis of the financial feasibility of the project. Also, a Source and Use of Funds statement for all project funding must be included. (0–10 points)

d. Criterion IV: Significant and Beneficial Impact (Maximum: 20 points)

(1) *Significant and beneficial impact (sub-rating: 0–5 points)*

The proposed project will produce permanent and measurable results that will reduce the incidence of poverty and TANF assistance in the community. (0–3 points)

The OCS grant funds, in combination with private and/or other public resources, are targeted into low-income communities, distressed communities, and/or designated Empowerment Zones and Enterprise Communities. (0–2 points)

(2) *Community empowerment consideration and partnership with child support enforcement agency (sub-rating: 0–5 points)*

Special consideration will be given to applicants who are located in areas that are characterized by poverty and other indicators of socio-economic distress such as a poverty or TANF assistance rate of at least 20%, designation as an Empowerment Zone or Enterprise Community (EZ/EC), high levels of unemployment, high levels of incidences of violence, gang activity, crime, drug use, and low-income non-custodial parents of children receiving TANF. (0–3 points)

Applicants should document that they were involved in the preparation and implementation of a comprehensive community-based strategic plan to achieve both economic and human development in an integrated manner; and how the proposed project will support the goals of that plan. Also, applicants should document that they have entered into partnership agreements with local Child Support Enforcement agencies to increase capability of low-income parents and families to fulfill their parental responsibilities. (0–2 points)

Note: Applicants who have projects located in EZ/EC target areas or those who have included signed current agreements with child support enforcement agencies will automatically receive the maximum 2 points.

(3) *Cost-per-job (sub-rating: 0–5 points)*

During the project period, the proposed project will create new, permanent jobs or maintain permanent jobs for low-income residents at a cost-per-job below $15,000 in OCS funds *unless* there are extenuating circumstances, *e.g.*, Alaska where the cost of living is much higher.

Note: The maximum number of points will be given to those applicants proposing estimated cost-per-job for low-income residents of $10,000 or less of OCS requested funds. Higher cost-per-job estimates will receive correspondingly fewer points unless adequately justified by extenuating circumstances.

(4) *Career development opportunities (sub-rating: 0–5 points)*

The application documents that the jobs to be created for low-income people have career development opportunities which will promote self-sufficiency.

e. Criterion V: Public-Private Partnerships (Maximum: 20 Points)

(1) *Mobilization of resources: (sub-rating: 15 points)*

The application documents that the applicant will mobilize from public and/or private sources cash and/or in-kind contributions valued at an amount equal to the OCS funds requested.

Applicants documenting that the value of such contributions will be at least equal to the OCS funds requested will receive the maximum number of points for this sub-criterion. Lesser contributions will be given consideration based upon the value documented.

Note 1: Cash resources such as cash or loans contributed from all project sources (except for those contributed directly by the applicant) must be documented by letters of commitment from third parties making the contribution. Third party in-kind contributions such as equipment or real property contributed by the applicant or third parties must be documented by an inventory for equipment and a copy of deed or other legal document for real property. In addition, future or projected program income such as gross or net profits from the project or business operations will not be recognized as mobilized or contributed resources.

Note 2: Applicants under Sub-Priority Area 1.2 who have a signed, written agreement for a significant partnership role with Historically Black Colleges and Universities are deemed to have fully met this criterion and will receive the maximum number of points if they include the agreement with the HBCU.

(2) *Integration/coordination of services: (sub-rating: 5 points)*

The applicant demonstrates a commitment to or agreements with local agencies responsible for administering child support enforcement, employment, education, and training programs to ensure that welfare recipients, at-risk youth, displaced workers, public housing tenants, homeless and low-income individuals, and low-income non-custodial parents will be trained and placed in the newly created jobs. The applicant provides written agreements from the local TANF or other employment, education and training office, and child support enforcement agency indicating what actions will be taken to integrate/coordinate services that relate directly to the project for which funds are being requested. (0–2 points)

Specifically, the agreements should include: (1) the goals and objectives that the applicant and the TANF or other employment, education and training office and/or child support enforcement agency expect to achieve through their collaboration; (2) the specific activities/actions that will be taken to integrate/coordinate services on an on-going basis; (3) the target population that this collaboration will serve; (4) the mechanism(s) to be used in integrating/coordinating activities; (5) how those activities will be significant in relation to the goals and objectives to be achieved through the collaboration; and (6) how those activities will be significant in relation to their impact on the success of the OCS-funded project. (0–2 points)

The applicant should also provide documentation that illustrates the organizational experience related to the employment education and training program. (Refer to Criterion II for guidelines.) (0–1 point)

f. Criterion VI: Budget Appropriateness and Reasonableness (Maximum: 5 points)

Funds requested are commensurate with the level of effort necessary to accomplish the goals and objectives of the project. (0–2 points)

The application includes a detailed budget breakdown for each of the budget categories in the SF–424A. The applicant presents a reasonable administrative cost. (0–2 points)

The estimated cost to the government of the project also is reasonable in relation to the anticipated results. (0–1 point)

2. Criteria for Review and Evaluation of Applications Submitted Under Sub-Priority Area 1.3

a. Criterion I: Analysis of Need (Maximum: 15 points)

The application documents that there are clearly identified needs in a low-income community not being effectively addressed. (0–10 points)

Most recent available statistics and other information are provided in support of its contention. (0–5 points)

b. Criterion II: Organizational Capability and Capacity (Maximum: 20 points)

(1) *Organizational experience in program area (sub-rating: 5 points)*

Each applicant must briefly show why its organization can successfully implement the project for which it is requesting funds. (0–5 points)

(2) *Management capacity (sub-rating: 5 points)*

Applicants must fully detail their ability to implement sound and effective management practices and if they have been recipients of other Federal or other governmental grants, they must also detail that they have consistently complied with financial and program progress reporting and audit requirements. (0–3 points)

Applicants should submit any available documentation on their management practices and progress reporting procedures along with a statement by a Certified or Licensed Public Accountant as to the sufficiency of the applicant's financial management system to protect adequately any Federal funds awarded under the application submitted. (0–2 points)

Note: The documentation of the applicant's management practices, etc., and statement from the accountant on the financial management system must address the applicant organization's own internal system rather than an external system of an affiliate, partner, management support organization, etc.

(3) *Staffing (sub-rating: 5 points)*

The application must fully describe (*e.g.*, resumes) the experience and skills of key staff showing that they are not only well qualified but that their professional capabilities are relevant to the successful implementation of the project.

(4) *Staffing responsibilities (sub-rating: 5 points)*

The application must describe how the assigned responsibilities of the staff are appropriate to the tasks identified for the project.

c. Criterion III: Project Design, Implementation and Evaluation (Maximum: 30 Points)

(1) *Project implementation component (sub-rating: 25 points)*

The work plan must address a clearly identified need in the low-income community as described in Criterion I. The plan must include a methodology to evaluate the feasibility of potential projects that conform to the type of projects and activities allowable under Sub-Priority Areas 1.1, 1.2, and 1.4. (0–10 points)

It must set forth realistic quarterly time schedules of work tasks by which the objectives (including the development of a business plan and mobilization of resources) will be accomplished. Because quarterly time schedules are used by OCS as a key instrument to monitor progress, failure to include these time targets will seriously reduce an applicant's point score in this criterion. (0–10 points)

It must define critical issues or potential problems that might impact negatively on the project and it must indicate how the project objectives will be attained notwithstanding any such potential problems. (0–5 points)

(2) *Evaluation component (sub-rating: 5 points)*

All proposals should include a self-evaluation component. The evaluation data collection and analysis procedures should be specifically oriented to assess the degree to which the stated goals and objectives are achieved. (0–3 points)

Qualitative and quantitative measures reflective of the scheduling and task delineation in (1) above should be used to the maximum extent possible. This

component should indicate the ways in which the potential grantee would integrate qualitative and quantitative measures of accomplishment and specific data into its program progress reports that are required by OCS from all organizations receiving pre-developmental grants. (0–2 points)

d. Criterion IV: Significant and Beneficial Impact (Maximum: 25 Points)

Funding under this sub-priority area is targeted to result in a business plan for a proposed project. The proposed project around which the business plan is to be developed with the use of OCS grant funds must be targeted into low-income communities, and/or designated Empowerment Zones or Enterprise Communities with the goals of increasing the economic conditions and social self-sufficiency of residents. Also, the project proposes to produce permanent and measurable results that will reduce the incidence of poverty and number of TANF recipients in the low-income area targeted. (0–20 points)

Note: This sub-priority area permits applicants to conduct several feasibility studies related to various potential projects. However, on completion of the studies, one proposed project must be selected and a business plan prepared for the selected project.

The activity targets mobilization of non-discretionary program dollars from private sector individuals, public resources, corporations, and foundations including the utilization of Historically Black Colleges and Universities, if the proposed project is implemented. (0–5 points)

e. Criterion V: Budget Appropriateness and Reasonableness (Maximum: 10 points)

Funds requested are commensurate with the level of effort necessary to accomplish the goals and objectives of the project. The estimated cost to the government of the project also is reasonable in relation to the anticipated results. (0–5 points)

The application includes a narrative detailed budget breakdown for each of the budget categories in the SF 424–A. The applicant presents a reasonable administrative cost. (0–5 points)

3. Criteria for Review and Evaluation of Applications Submitted Under Sub-Priority Area 1.5

a. Criterion I: Organizational Experience in Program Area and Staff Responsibilities (Maximum: 20 points)

(1) *Organizational experience in program area (sub-rating: 0–10 points)*

Applicant has documented the capability to provide leadership in solving long-term and immediate problems locally and/or nationally in such areas as business development, commercial development, organizational and staff development, board training, and micro-entrepreneurship development. (0–2 points)

Applicant must document a capability (including access to a network of skilled individuals and/or organizations) in two or more of the following areas: Business management, including strategic planning and fiscal management; finance, including development of financial packages and provision of financial/accounting services; and regulatory compliance, including assistance with zoning and permit compliance. (0–2 points)

Further, the applicant has the demonstrated ability to mobilize dollars from sources such as the private sector (corporations, banks, foundations, etc.) and the public sector, including state and local governments. (0–2 points)

Applicant also demonstrates that it has a sound organizational structure and proven organizational capability as well as an ability to develop and maintain a stable program in terms of business, physical or community development activities that have provided permanent jobs, services, business development opportunities, and other benefits to poverty community residents. (0–2 points)

Applicants must indicate why they feel that their successful experiences would be of assistance to existing grantees that are experiencing difficulties in implementing their projects. (0–2 points)

(2) *Staff skills, resources and responsibilities (sub-rating 0–10 points)*

The application describes in brief resume form the experience and skills of the project director who is not only well qualified, but who has professional capabilities relevant to the successful implementation of the project. If the key staff person has not yet been identified, the application contains a comprehensive position description that indicates that the responsibilities to be assigned to the project director are relevant to the successful implementation of the project. (0–5 points)

The applicant has adequate facilities and resources (*i.e.* space and equipment) to successfully carry out the work plan. (0–3 points)

The assigned responsibilities of the staff are appropriate to the tasks identified for the project and sufficient time of senior staff will be budgeted to assure timely implementation and cost effective management of the project. (0–2 points)

b. Criterion II: Work Program (Maximum: 30 points)

Based upon the applicant's knowledge and experience related to OCS' Discretionary Grants Program (particularly community economic development), the application should demonstrate in some specificity a thorough understanding of the problems a grantee may encounter in implementing a successful project. (0–15 points)

The application should include a strategy for assessing the specific nature of the problems, outlining a course of action and identifying the resources required to resolve the problems. (0–15 points)

c. Criterion III: Significant and Beneficial Impact (Maximum: 30 points)

Project funds under this sub-priority area must be used for the purposes of transferring expertise directly, or by a contract with a third party, to other OCS funded grantees. Applicants must document how the success or failure of collaboration with these grantees will be documented. (0–15 points)

Applicants must demonstrate an ability to disseminate results on the kinds of programmatic and administrative expertise transfer efforts in which they participated and successful strategies that they may have developed to share expertise with grantees during the grant period. (0–10 points)

Applicants must also state whether the results of the project will be included in a handbook, a progress paper, an evaluation report, a general manual, or seminars/workshops, and why the particular methodology chosen would be most effective. (0–5 points)

d. Criterion IV: Public-Private Partnerships (Maximum: 15 points)

The applicant demonstrates that it has worked with local, regional, state or national offices to ensure that TANF recipients, at-risk youth, displaced workers, public housing tenants, low-income noncustodial parents, homeless and otherwise low-income individuals have been trained and placed in newly created jobs. (0–10 points)

Applicant should demonstrate how it will design a comprehensive strategy which makes use of other available resources to resolve typical and recurrent grantee problems. (0–5 points)

e. Criterion V: Budget Appropriateness and Reasonableness (Maximum: 5 points)

Applicant documents that the funds requested are commensurate with the level of effort necessary to accomplish the goals and objectives of the project. The application includes a detailed budget breakdown for each of the appropriate budget categories in the SF–424A. (0–3 points)

The estimated cost to the government of the project also is reasonable in relation to the anticipated results. (0–2 points)

4. Criteria for Review and Evaluation of Applications Submitted Under Sub-Priority Area 1.6

a. Criterion I: Need for Assistance (Maximum: 10 points)

The application documents that the project addresses a vital, nationwide need related to the purposes of Priority Area 1.0 and provides data and information in support of its contention.

b. Criterion II: Organizational Experience in Program Area and Staff Responsibilities (Maximum: 20 points)

(1) *Organizational experience*

Applicant has documented the capability to provide leadership in solving long-term and immediate problems locally and/or nationally in such areas as business development, commercial development, organizational and staff development, board training, and micro-entrepreneurship development. Applicant must document a capability (including access to a network of skilled individuals and/or organizations) in two or more of the following areas: Business management, including strategic planning and fiscal management; finance, including development of financial packages and provision of financial/accounting services; and regulatory compliance, including assistance with zoning and permit compliance. (0–10 points)

(2) *Staff skills*

The applicant's proposed project director and primary staff are well qualified and their professional experiences are relevant to the successful implementation of the proposed project. (0–10 points)

c. Criterion III: Work Plan (Maximum: 35 points)

Based upon the applicant's knowledge and experience related to OCS' Discretionary Grants Program (particularly community economic development), the applicant must develop and submit a detailed and specific work plan that is both sound and feasible. Specifically, the work plan should:

(1) Demonstrate that all activities are comprehensive and nationwide in scope, adequately described, and appropriately related to the goals of the program. (0–10 points)

(2) Demonstrate in some specificity a thorough understanding of the kinds of training and technical assistance that can be provided to the network of community development corporations. (0–10 points)

(3) Delineate the tasks and sub-tasks involved in the areas necessary to carry out the responsibilities, i.e. training, technical assistance, research, outreach, seminars, etc. (0–5 points)

(4) State the intermediate and end products to be developed by task and sub-task. (0–5 points)

(5) Provide realistic time frames and a chronology of key activities for the goals and objectives. (0–5 points)

d. Criterion IV: Significant and Beneficial Impact (Maximum: 25 points)

Project funds under this sub-priority area must be used for the purpose of providing training and technical assistance on a national basis to the network of community development corporations.

The applicant should describe how:

(1) The project will assure long-term program and management improvements for community development corporations. (0–10 points)

(2) The project will impact on a significant number of community development corporations. (0–10 points)

(3) The project will leverage or mobilize significant other non-federal resources for the direct benefit of the project. (0–5 points)

e. Criterion V: Budget Reasonableness (Maximum: 10 points)

(1) *The resources requested are reasonable and adequate to accomplish the project. (0–5 points)*

(2) *Total costs are reasonable and consistent with anticipated results. (0–5 points)*

5. Criteria for Review and Evaluation of All Applications Under Priority Area 2.0

a. Criterion I: Analysis of Need (Maximum: 5 points)

The application documents that the project addresses a vital need in a distressed community and provides statistics and other data and information in support of its contention.

b. Criterion II: Organizational Experience in Program Area and Staff Responsibilities (Maximum: 15 points)

(1) *Organizational Experience in Program Area (sub-rating: 0–5 points)*

Documentation provided indicates that projects previously undertaken have been relevant and effective and have provided permanent benefits to the low-income population.

Organizations that propose providing training and technical assistance have detailed competence in the specific program priority area and as a deliverer with expertise in the fields of training and technical assistance. If applicable, information provided by these applicants also addresses related achievements and competence of each cooperating or sponsoring organization.

(2) *Staff Skills, Resources and Responsibilities (sub-rating 0–10 points)*

The application describes in brief resume form the experience and skills of the project director who is not only well qualified, but whose professional capabilities are relevant to the successful implementation of the project. If the key staff person has not yet been identified, the application contains a comprehensive position description that indicates that the responsibilities to be assigned to the project director are relevant to the successful implementation of the project. The applicant has adequate facilities and resources (i.e. space and equipment) to successfully carry out the work plan. The assigned responsibilities of the staff are appropriate to the tasks identified for the project and sufficient time of senior staff will be budgeted to assure timely implementation and cost effective management of the project.

c. Criterion III: Project Implementation (Maximum: 25 points)

The work plan is both sound and feasible. The project is responsive to the needs identified in the Analysis of Need. It sets forth realistic quarterly time targets by which the various tasks will be completed. Critical issues or potential problems that might impact negatively on the project are defined and the project objectives can be reasonably attained despite such potential problems.

d. Criterion IV: Significant and Beneficial Impact (Maximum: 30 points)

The application contains a full and accurate description of the proposed use of the requested financial assistance. The proposed project will produce permanent and measurable results that will reduce the incidence of poverty in

the areas targeted and significantly enhance the self-sufficiency of program participants. Results are quantifiable in terms of program area expectations, e.g., number of units of housing rehabilitated, agricultural and non-agricultural job placements, etc. The OCS grant funds, in combination with private and/or other public resources, are targeted into low-income and/or distressed communities and/or designated Empowerment Zones and Enterprise Communities.

e. Criterion V: Public-Private Partnerships (Maximum: 20 points)

The application documents that the applicant will mobilize from public and/or private sources cash and/or in-kind contributions valued at an amount equal to the OCS funds requested. Applicants documenting that the value of such contributions will be at least equal to the OCS funds requested will receive the maximum number of points for this Criterion. Lesser contributions will be given consideration based upon the value documented.

f. Criterion VI: Budget Appropriateness and Reasonableness (Maximum: 5 points)

Funds requested are commensurate with the level of effort necessary to accomplish the goals and objectives of the project. The application includes a narrative detailed budget break-down for each of the budget categories in the SF–424A. The applicant presents a reasonable administrative cost. The estimated cost to the government of the project also is reasonable in relation to the anticipated results.

Part E—Application Procedures

1. Availability of Forms

For purposes of this announcement, all applicants will use the following forms: SF 424; SF 424A; SF 424B.

Applications proposing construction projects will present all required financial data using SF–424A. Instructions for completing the SF–424, SF–424A, and SF–424B are found in Attachments B, C, and D. These forms may be photocopied for this application.

Part F contains instructions for the project abstract and project narrative. They will be submitted on plain bond paper along with the SF–424 and related forms.

Attachment M, Applicant's Checklist, provides a checklist to aid applicants in preparing a complete application package for OCS.

The applicant must be aware that in signing and submitting the application for this award, it is certifying that it will comply with the Federal requirements concerning the following regulations: Drug-Free Workplace, Attachment E; Debarment, Attachment F; and Environmental Tobacco Smoke, Attachment J.

2. Intergovernmental Review

This program is covered under Executive Order 12372, Intergovernmental Review of Federal Programs, and 45 CFR Part 100, Intergovernmental Review of Department of Health and Human Services Programs and Activities. Under the Order, states may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

As of March 5, 1999 the following jurisdictions have elected NOT to participate in the Executive Order process. Applicants from these jurisdictions or for projects administered by Federally-recognized Indian Tribes need take no action in regard to E.O. 12372:

Alabama, Alaska, Colorado, Connecticut, Hawaii, Idaho, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, American Samoa and Palau.

Applicants should contact their SPOCs as soon as possible to alert them of the prospective applications and receive any necessary instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a, and submit a copy of the letter along with its application to OCS.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline date to comment on proposed new or competing continuation awards.

The SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official state process recommendations which they intend to trigger the ''accommodate or explain'' rule.

When comments are submitted directly to ACF, they should be addressed to: Department of Health and Human Services, Administration for Children and Families, Office of Grants Management/OCSE, 4th Floor West, Aerospace Center, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447.

A list of the Single Points of Contact for each state and territory is included as Attachment G of this announcement.

3. Application Consideration

Applications that meet the screening requirements in sections 4.a and b. below may be reviewed competitively. Such applications will be referred to reviewers for a numerical score and explanatory comments based solely on responsiveness to program priority area guidelines and evaluation criteria published in this announcement.

Applications submitted under all priority areas (with the exception of Sub-Priority Area 1.6) will be reviewed by persons outside of the Office of Community Services. The results of these reviews will assist the Director and OCS program staff in considering competing applications. Reviewers' scores will weigh heavily in funding decisions but will not be the only factors considered. Applications generally will be considered in order of the average scores assigned by reviewers. However, highly ranked applications are not guaranteed funding since the Director may also consider other factors deemed relevant including, but not limited to, the timely and proper completion of projects funded with OCS funds granted in the last five (5) years; comments of reviewers and government officials; staff evaluation and input; geographic distribution; previous program performance of applicants; compliance with grant terms under previous DHHS grants; audit reports; investigative reports; and applicant's progress in resolving any final audit disallowances on previous OCS or other Federal agency grants. Applicants with three or more active OCS grants at the time of review may be denied funding. In addition, for applications received under 1.0, OCS will consider the geographic distribution of funds among states and the relative proportion of funding among rural and urban areas in accordance with Section 681(b)(1)(D) of the Act.

OCS reserves the right to discuss applications with other Federal or non-Federal funding sources to ascertain the applicant's performance record.

4. Criteria for Screening Applicants

a. Initial screening

All applications that meet the published deadline for submission will be screened to determine completeness

and conformity to the requirements of this announcement. Only those applications meeting the following requirements will be reviewed and evaluated competitively. Others will be returned to the applicants with a notation that they were unacceptable.

(1) The application must contain an Application for Federal Assistance (SF–424), a budget (SF–424A), and signed Assurances (SF 424B) completed according to instructions published in Parts F and G and Attachments B, C, and D of this Program Announcement.

(2) A project abstract must also accompany the standard forms.

(3) The SF–424 and the SF–424B must be signed by an official of the organization applying for the grant who has authority to obligate the organization legally.

(4) The application must be submitted for consideration under one priority area only.

b. Pre-review

Applications that pass the initial screening will be forwarded to reviewers and/or OCS staff prior to the programmatic review to verify that the applications comply with this Program Announcement in the following areas:

(1) *Eligibility:* Applicant meets the eligibility requirements for the priority area under which funds are being requested. Proof of non-profit status, *i.e.* the IRS determination letter of tax exemption, must be included in the appendices of the project narrative where applicable. Applicants that do not submit proof of non-profit status will be disqualified. Applicants must also be aware that the applicant's legal name as required in SF–424 (Item 5) *must match* that listed as corresponding to the Employer Identification Number (Item 6).

(2) *Number of Projects:* An application may contain only one project under Sub-Priority Areas 1.1, 1.2 and 1.4. However, an application may contain more than one project under Sub-Priority Areas 1.3, 1.5, and 1.6 where applicants are researching various opportunities, sharing administrative and management expertise with current OCS grantees, providing assistance to current OCS grantees, providing training and/or technical assistance current OCS grantees, including the organization of seminars and other activities to assist community development corporations and this project must be identified as responding to one of the program priority areas stated in this Announcement.

(3) *Grant amount:* The amount of funds requested does not exceed the limits indicated in Part B, 2, b or the appropriate priority area.

(4) *Written Agreement When Applicant Proposes to Make Equity Investment or Loan:* (Sub-Priority Areas 1.1, 1.2 and 1.4); The application contains a written third party agreement, or a discussion of a proposed agreement, signed by the applicant and the third party that includes all of the elements required in Part B, item 9.

An application will be disqualified if it does not conform to one or more of the above requirements.

c. Panel Reviews

Applications that pass the pre-rating review will be assessed and scored by panels of reviewers. Each reviewer will give a numerical score for each application reviewed. These numerical scores will be supported by explanatory statements on a formal rating form describing major strengths and weaknesses under each applicable criterion published in the announcement.

The panelists will use the following criteria coupled with the specific requirements contained under each program priority area as described in Part C.

Part F—Contents of Application and Receipt Process

1. Contents of Application

Each submission should include one signed original and four additional copies of the application. The application package including the narrative should not exceed 65 pages for the applications submitted under Sub-Priority Areas 1.1, 1.2 and 1.4 and 30 pages under the other sub-priority areas. This does not include appendices listed below. Application pages should be numbered sequentially throughout the application package, beginning with an abstract of the proposed project as page number one. Each application must include all of the following, in the order listed below:

a. Table of Contents;

b. A Project Abstract—A paragraph that succinctly describes the project in 500 characters or less.

c. Completed Standard Form 424 (Attachment B) that has been signed by an official of the organization applying for the grant who has authority to obligate the organization legally.

d. A Standard Form 424A—Budget Information—Non-construction Programs (Attachment C).

e. A narrative budget justification for each object class category required under Section B, SF–424A.

f. A Project Narrative. The project narrative must address the specific concerns mentioned under the relevant priority area description in Part C. The narrative should also provide information on how the application meets the evaluation criteria in Part D and Guidelines for a Business Plan (Attachment K) of the Program Announcement.

g. A Standard Form 424B Assurances—Non-Construction (Attachment D)—All applicants, whether or not their project involves construction, must file the Standard Form 424B. Applicants must sign and return this form with their applications.

h. Certification Regarding Lobbying—(Attachment H)—Prior to receiving an award in excess of $100,000, applicants must sign and return an executed copy of the lobbying certification.

i. Disclosure of Lobbying Activities, SF–LLL (Attachment H)—Fill out, sign and date the form.

j. DHHS Regulations Applying to All Applicants/Grantees Under the Fiscal Year 2000 Discretionary Grants Program (Attachment I)—By signing and submitting the application, applicant is certifying that it will comply with these regulations.

k. Certification Regarding Environmental Tobacco Smoke (Attachment J)—Applicants must make the appropriate certification of their compliance with the Pro-Children Act of 1994. By signing and submitting the applications, applicants are providing the certification regarding environmental tobacco smoke and need not mail back the certification with their applications.

l. Certification Regarding Drug-Free Workplace Requirement: By signing and submitting the application, applicant is certifying that it will comply with this regulation.

m. Certification Regarding Debarment, Suspension, and Other Responsibility Matters: By signing and submitting the application, applicant is certifying that it will comply with this regulation.

n. Appendices should include: Proof of non-profit status (a copy of the applicant's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in Section 501(C)(3) of the IRS Code *or* a copy of the currently valid IRS tax exemption certificate); a copy of the Articles of Incorporation bearing the seal of the State in which the corporation or association is domiciled; a listing of the current Board of Directors' names, titles and addresses (Note: If the applicant is proposing an equity transaction, this is also needed for the third party organization); résumés of the project director and other key management team members; written

agreements, *i.e.*, third party agreements, coordination with TANF, etc.; a copy of the submission to the State Single Point of Contact, if applicable; Single Point of Contact comments, where applicable; certification regarding anti-lobbying activities; and a disclosure of lobbying activities.

2. Acknowledgment of Receipt

All applicants will receive an acknowledgment notice with an assigned identification number. Applicants are requested to supply a self-addressed mailing label with their application that can be attached to this acknowledgment notice. The identification number and the program priority area letter code must be referred to in all subsequent communications with OCS concerning the application. If an acknowledgment is not received within three weeks after the deadline date, please notify ACF by telephone at (202)401–5103.

(Note: To facilitate receipt of this acknowledgment from ACF, applicant should include a cover letter with the application containing an E-mail address and facsimile (FAX) number if these items are available to applicant.)

Part G—Instructions for Completing Application Package

It is suggested that the applicant reproduce the SF–424 and SF–424A, and type its organization's legal name on the copies. If an item on the SF–424 cannot be answered or does not appear to be related or relevant to the assistance requested, write NA for Not Applicable.

Prepare your application in accordance with the standard instructions given in Attachments B and C corresponding to the forms, as well as the OCS specific instructions set forth below:

1. SF–424 Application for Federal Assistance

Item 1. For the purposes of this announcement, all proposals are considered Applications; there are no Pre-Applications. For the purpose of this announcement, construction projects involve land improvements and development or major renovation of (new or existing) facilities and buildings, including their improvements, fixtures and permanent attachments. All others are considered non-construction. Check the appropriate box under Application. Whether applications involve construction or non-construction projects, all applicants are required to complete the Budget Information—Non-construction Programs sections of SF–424A.

Items 5 and 6. The legal name of the applicant must match that listed as corresponding to the Employer Identification Number. Where the applicant is a previous Department of Health and Human Services grantee, enter the Central Registry System Employee Identification Number (EIN) and the Payment Identifying Number (PIN), if one has been assigned, in the Block entitled Federal Identifier located at the top right hand corner of the form.

Item 7. If the applicant is a non-profit corporation, enter N in the box and specify non-profit corporation in the space marked Other. Any non-profit organization submitting an application must submit proof of its non-profit status in its applications at time of submission.

Item 9. Enter DHHS—ACF/OCS.

Item 10. The Catalog of Federal Domestic Assistance number for OCS programs covered under this Announcement is 93.570. The title is CSBG Discretionary Awards.

Item 11. In addition to a brief descriptive title of the project, indicate one of the following program priority areas for which funds are being requested.

UR—Sub-Priority Area 1.1. Urban and Rural Community Economic Development (Operational)

HB—Sub-Priority Area 1.2. Urban and Rural Community Economic Development (HBCU Set-Aside)

PD Sub-Priority Area 1.3. Urban and Rural Community Economic Development (Pre-Developmental Set-Aside)

DD—Sub-Priority Area 1.4. Urban and Rural Community Economic Development (Developmental Set-Aside)

AM—Sub-Priority Area 1.5. Administrative and Management (Set-Aside)

UT—Sub-Priority Area 1.6. Training and Technical Assistance (Set-Aside)

RF—Priority Area 2.0. Rural Community Facilities Development (Water and Waste Water Treatment Systems Development)

2. SF–424A—Budget Information—Non-Construction Programs

See Instructions accompanying this form as well as the instructions set forth below:

In completing these sections, the ''Federal Funds'' budget entries will relate to the requested OCS discretionary funds only, and Non-Federal will include mobilized funds from all other sources—applicant, state, local, and other. Federal funds other than requested OCS Discretionary funding should be included in Non-Federal entries.

The budget forms in SF–424A are only to be used to present grant administrative costs and major budget categories. Financial data that is generated as part of a project Business Plan or other internal project cost data must be separate and should appear as part of the project Business Plan or other project implementation data.

Sections A and D of SF–424A must contain entries for both Federal (OCS) and non-Federal (mobilized) funds. Section B contains entries for Federal (OCS) funds only. Clearly identified continuation sheets in SF–424A format should be used as necessary.

Section A—Budget Summary

Lines 1–4

—Column (a): Line 1 Enter CSBG Discretionary;
—Column (b): Line 1 Enter 93.570
—Columns (c) and (d): Leave Blank
—Columns (e) thru (g):Enter the appropriate amounts needed to support the project for the budget period.

Line 5 Enter the figures from Line 1 for all columns completed as required, (c), (d), (3), (f), and (g).

Section B—Budget Categories

Allowability of costs are governed by applicable cost principles set forth in 45 CFR Parts 74 and 92. A budget narrative must be submitted that includes the appropriate justifications as stated.

This section should contain entries for OCS funds only. For all projects, this first budget period will be entered in Column (1).

Budget estimates for administrative costs must be supported by adequate detail for the grants officer to perform a cost analysis and review. Adequately detailed calculations for each budget object class are those which reflect estimation methods, quantities, unit costs, salaries, and other similar quantitative detail sufficient for the calculation to be duplicated. For any additional object class categories included under the object class *other*, identify the additional object class(es) and provide supporting calculations.

Supporting narratives and justifications are required for each budget category, with emphasis on unique/special initiatives; large dollar amounts; local, regional, or other travel; new positions; and major equipment purchases.

A detailed itemized budget with a separate budget justification for each major item should be included as indicated below:

Line 6a

Personnel—Enter the total costs of salaries and wages.

Justification—Identify the project director and staff. Specify by title or name the percentage of time allocated to the project, the individual annual salaries and the cost to the project (both Federal and non-Federal) of the organization's staff who will be working on the project.

Line 6b

Fringe Benefits—Enter the total costs of fringe benefits unless treated as part of an approved indirect cost rate which is entered on Line 6j.

Justification—Enter the total costs of fringe benefits, unless treated as part of an approved indirect cost rate. Provide a breakdown of amounts and percentages that comprise fringe benefit costs.

Line 6c

Travel—Enter total cost of all travel by employees of the project. Do not enter costs for consultant's travel.

Justification—Include the name(s) of traveler(s), total number of trips, destinations, length of stay, mileage rate, transportation costs and subsistence allowances. Traveler must be a person listed under the personnel line or employee being paid under non-federal share. (Note: Local transportation and Consultant travel costs are entered on Line 6h.)

Line 6d

Equipment—Enter the total estimated costs for all non-expendable personal property to be acquired by the project. *Equipment* means tangible nonexpendable personal property, including exempt property, charged directly to the award having a useful life of more than one year and an acquisition cost of $5000 or more per unit. However, consistent with recipient policy, lower limits may be established.

Justification—Provide breakdown of cost per item. Items that cost less than $5,000 should be included under Supplies.

Line 6e

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

Justification—Provide a general description as to what is being purchased such as type of supplies, office, classroom, medical, etc. Also property that is not equipment and costs less than $5,000 per item.

Line 6f

Contractual—Enter the total costs of all contracts, including (1) procurement contracts (except those which belong on other lines such as equipment, supplies, etc.) and (2) contracts with secondary recipient organizations including delegate agencies and specific projects(s) or businesses to be financed by the applicant.

Justification—Contractual cannot be a person—it must be the name of an organization, firm, etc. Consultant cost goes in—other.

Line 6g

Construction—Enter the estimated costs of renovation, repair, or new construction. Identify the type of construction activity and costs associated, i.e., concrete, HVAC, electrical, etc. Provide narrative justification and breakdown of costs.

Line 6h

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

Justification—Provide as much detail as you can. Some items may have to be defined more than others.

Line 6j

Indirect Charges—Enter the total amount of indirect costs. This line should be used only when the applicant currently has an indirect cost rate approved by DHHS or other Federal agencies.

If the applicant organization is in the process of initially developing or renegotiating a rate, it should, immediately upon notification that an award will be made, develop a tentative indirect cost rate proposal based on its most recently completed fiscal year in accordance with the principles set forth in the pertinent *DHHS Guide for Establishing Indirect Cost Rates* and submit it to the appropriate DHHS Regional Office. It should be noted that when an indirect cost rate is requested, those costs included in the indirect cost pool cannot be also budgeted or charged as direct costs to the grant. Indirect costs consistent with approved Indirect Cost Rate Agreements are allowable.

Section C—Non-Federal Resources

This section is to record the amounts of non-Federal resources that will be used to support the project. Non-Federal resources mean other than OCS funds for which the applicant is applying. Therefore, mobilized funds from other Federal programs, such as the Job Training Partnership Act program, should be entered on these lines. Provide a brief listing of the non-Federal resources on a separate sheet and describe whether it is a grantee-incurred cost or a third-party in-kind contribution. The firm commitment of these resources must be documented and submitted with the application in order to be given credit in the Public-Private Partnerships Criterion.

Except in unusual situations, this documentation must be in the form of letters of commitment from the organization(s)/ individuals from which funds will be received.

(Note: Even though there is no matching requirements for the Discretionary Grants Program, grantees will be held accountable for any match, cash or in-kind contribution proposed or pledged as part of an approved application.)

Part H—Post Award Information and Reporting Requirements

1. Notification of Grant Award

Following approval of the applications selected for funding, notice of project approval and authority to draw down project funds will be made in writing. The official award document is the Financial Assistance Award that provides the amount of Federal funds approved for use in the project, the budget period for which support is provided, the terms and conditions of the award, the total project period for which support is contemplated, and the total financial participation from the award recipient.

General Conditions and Special Conditions (where the latter are warranted) which will be applicable to grants, are subject to the provisions of 45 CFR Parts 74 and 92.

2. Attendance at OCS Training Conference

The Executive Director and/or Project Director will be required to attend a two-day national workshop in Washington, DC. The project budget must include funds for travel to and attendance at this conference.

3. Reporting Requirements

Grantees will be required to submit semi-annual progress and financial

reports (SF–269) as well as a final progress and financial report.

Under the Paperwork Reduction Act of 1995, Public Law 104–13, 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. This program announcement does not contain information collection requirements beyond those approved for ACF grant applications under OMB Control Number 0970–0062.

4. Audit Requirements

Grantees are subject to the audit requirements in 45 CFR Parts 74 and 92 and OMB Circular A–133. If an applicant will not be requesting indirect costs, it should anticipate in its budget request the cost of having an audit performed at the end of the grant period.

Section 319 of Public Law 101–121, signed into law on October 23, 1989, imposes prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal contracts, grants, cooperative agreements, and loans. It provides limited exemptions for Indian tribes and tribal organizations. Current and prospective recipients (and their subtier contractors and/or grantees) are prohibited from using appropriated funds for lobbying Congress or any Federal agency in connection with the award of a contract, grant, cooperative agreement or loan. In addition, for each award action in excess of $100,000 (or $150,000 for loans) the law requires recipients and their subtier contractors and/or subgrantees (1) to certify that they have neither used nor will use any appropriated funds for payment to lobbyists, (2) to submit a declaration setting forth whether payments to lobbyists have been or will be made out of nonappropriated funds and, if so, the name, address, payment details, and purpose of any agreements with such lobbyists whom recipients or their subtier contractors or subgrantees will pay with the *nonappropriated* funds and (3) to file quarterly up-dates about the use of lobbyists if an event occurs that materially affects the accuracy of the information submitted by way of declaration and certification. The law establishes civil penalties for noncompliance and is effective with respect to contracts, grants, cooperative agreements and loans entered into or made on or after December 23, 1989. See Attachment H for certification and disclosure forms to be submitted with the applications for this program.

5. Applicable Federal Regulations

Attachment I provides a list of the regulations that apply to all applicants/grantees under the FY 2000 Discretionary Grants Program.

Dated: August 11, 1999.

Donald Sykes,

Director, Office of Community Services.

Attachments

A—1999 Poverty Income Guidelines
B—Standard Form 424
C—Standard Form 424A
D—Standard Form 424B
E—Certification Regarding Drug-Free Workplace
F—Certification of Debarment
G—List of Single Points of Contact
H—Certification Regarding Lobbying and Disclosure of Lobbying Activities
I—DHHS Regulations Which Apply to all Applicants/Grantees Under The Fiscal Year 2000 Discretionary Grants Program
J—Certification of Environmental Tobacco Smoke
K—Business Plan
L—Table of Standard Industrial Codes and Occupational Classification
M—Applicant's Checklist

Attachment A

1999 Poverty Guidelines for the 48 Contiguous States and the District of Columbia

Size of family unit	Poverty guideline
1	$8,240
2	11,060
3	13,880
4	16,700
5	19,520
6	22,340
7	25,160
8	27,980

For family units with more than 8 members, add $2,820 for each additional member. (The same increment applies to smaller family sizes also, as can be seen in the figures above).

1999 Poverty Guidelines for Alaska

Size of family unit	Poverty guideline
1	$10,320
2	13,840
3	17,360
4	20,880
5	24,440
6	27,920
7	31,440
8	34,960

For family units with more than 8 members, add $3,520 for each additional member. (The same increment applies to smaller family sizes also, as can be seen in the figures above).

1999 Poverty Guidelines for Hawaii

Size of family unit	Poverty guideline
1	$9,490
2	12,730
3	15,970
4	19,210
5	22,450
6	25,690
7	28,930
8	32,170

For family units with more than 8 members, add $3,240 for each additional member. (The same increment applies to smaller family sizes also, as can be seen in the figures above).

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Attachment B

OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE

2. DATE SUBMITTED	Applicant Identifier	
3. DATE RECEIVED BY STATE	State Application Identifier	
4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier	

1. TYPE OF SUBMISSION:

Application
- ☐ **Construction**
- ☐ **Non-Construction**

Preapplication
- ☐ **Construction**
- ☐ **Non-Construction**

5. APPLICANT INFORMATION

Legal Name:

Organizational Unit:

Address *(give city, county, State, and zip code):*

Name and telephone number of person to be contacted on matters involving this application *(give area code)*

6. EMPLOYER IDENTIFICATION NUMBER *(EIN):*

☐☐ — ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: *(enter appropriate letter in box)* ☐

A. State
B. County
C. Municipal
D. Township
E. Interstate
F. Intermunicipal
G. Special District
H. Independent School Dist.
I. State Controlled Institution of Higher Learning
J. Private University
K. Indian Tribe
L. Individual
M. Profit Organization
N. Other (Specify) _____

8. TYPE OF APPLICATION:

☐ **New** ☐ **Continuation** ☐ **Revision**

If Revision, enter appropriate letter(s) in box(es) ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other*(specify):*

_____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

☐☐ — ☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT *(Cities, Counties, States, etc.):*

13. PROPOSED PROJECT		**14. CONGRESSIONAL DISTRICTS OF:**	
Start Date	Ending Date	a. Applicant	b. Project

15. ESTIMATED FUNDING:

a. Federal	$	.00
b. Applicant	$	.00
c. State	$	.00
d. Local	$	.00
e. Other	$	.00
f. Program Income	$	.00
g. TOTAL	$	.00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE _____

b. No. ☐ PROGRAM IS NOT COVERED BY E. O. 12372
☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ **Yes** **If "Yes," attach an explanation.** ☐ **No**

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.

a. Type Name of Authorized Representative	b. Title	c. Telephone Number
d. Signature of Authorized Representative		e. Date Signed

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Standard Form 424 (Rev. 7-97)
Prescribed by OMB Circular A-102

BILLING CODE 4184–01C

Attachment B (Page 2)

Instructions for the SF–424

Public reporting burden for this collection of information is estimated to average 45 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348–0043), Washington, DC 20503.

Please do not return your completed form to the Office of Management and Budget. Send it to the address provided by the sponsoring agency.

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item and Entry

1. Self-explanatory.
2. Date application submitted to Federal agency (or State if applicable) and applicant's control number (if applicable).
3. State use only (if applicable).
4. If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5. Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6. Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7. Enter the appropriate letter in the space provided.
8. Check appropriate box and enter appropriate letter(s) in the space(s) provided:

—''New'' means a new assistance award.
—''Continuation'' means an extension for an additional funding/budget period for a project with a projected completion date.
—''Revision'' means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.

9. Name of Federal agency from which assistance is being requested with this application.
10. Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11. Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
12. List only the largest political entities affected (e.g., State, counties, cities).
13. Self-explanatory.
14. List the applicant's Congressional District and any District(s) affected by the program or project.
15. Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16. Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether application is subject to the State intergovernmental review process.
17. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18. To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

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Attachment C

BUDGET INFORMATION - Non-Construction Programs

OMB Approval No. 0348-0044

SECTION A - BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1.		$	$	$	$	$
2.						
3.						
4.						
5. Totals		$	$	$	$	$

SECTION B - BUDGET CATEGORIES

6. Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY				Total
	(1)	(2)	(3)	(4)	(5)
a. Personnel	$	$	$	$	$
b. Fringe Benefits					
c. Travel					
d. Equipment					
e. Supplies					
f. Contractual					
g. Construction					
h. Other					
i. Total Direct Charges *(sum of 6a-6h)*					
j. Indirect Charges					
k. TOTALS *(sum of 6i and 6j)*	$	$	$	$	$
7. Program Income	$	$	$	$	$

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Prescribed by OMB Circular A-102

Attachment C (Page 2)

SECTION C - NON-FEDERAL RESOURCES				
(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS
8.	$	$	$	$
9.				
10.				
11.				
12. TOTAL *(sum of lines 8-11)*	$	$	$	$

SECTION D - FORECASTED CASH NEEDS					
	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
13. Federal	$	$	$	$	$
14. Non-Federal					
15. TOTAL *(sum of lines 13 and 14)*	$	$	$	$	$

SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT				
(a) Grant Program	FUTURE FUNDING PERIODS (Years)			
	(b) First	(c) Second	(d) Third	(e) Fourth
16.	$	$	$	$
17.				
18.				
19.				
20. TOTAL *(sum of lines 16-19)*	$	$	$	$

SECTION F - OTHER BUDGET INFORMATION	
21. Direct Charges:	22. Indirect Charges:
23. Remarks:	

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Standard Form 424A (Rev. 7-97) Page 2

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Instructions for the SF–424A

Public reporting burden for this collection of information is estimated to average 180 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348–0044), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a–k of Section B.

Section A. Budget Summary

Lines 1–4 Columns (a) and (b)

For applications pertaining to a single Federal grant program (Federal Domestic Assistance Catalog number) and not requiring a functional or activity breakdown, enter on Line 1 under Column (a) the Catalog program title and the Catalog number in Column (b).

For applications pertaining to a single program requiring budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the Catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the Catalog program title on each line in Column (a) and the respective Catalog number on each line in Column (b).

For applications pertaining to multiple programs where one or more programs require a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

Lines 1–4, Columns (c) through (g)

For new applications, leave Columns (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

For continuing grant program applications, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For supplemental grants and changes to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5—Show the totals for all columns used.

Section B Budget Categories

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1–4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Line 6a–i—Show the totals of Lines 6a to 6h in each column.

Line 6j—Show the amount of indirect cost.

Line 6k—Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount on the increase or decrease as shown in Columns (1)–(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

Line 7—Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount, Shown under the program narrative statement the nature and source of income. The estimated amount of program income may be considered by the Federal grantor agency in determining the total amount of the grant.

Section C. Non-Federal Resources

Lines 8–11—Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

Column (a)—Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

Column (b)—Enter the contribution to be made by the applicant.

Column (c)—Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

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

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

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

Section D. Forecasted Cash Needs

Line 13—Enter the amount of cash needed by quarter from the grantor agency during the first year.

Line 14—Enter the amount of cash from all other sources needed by quarter during the first year.

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

Section E. Budget Estimates of Federal Funds Needed for Balance of the Project

Lines 16–19—Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules ad necessary.

Line 20—Enter the total for each of the Columns (b)–(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

Section F. Other Budget Information

Line 21—Use this space to explain amounts for individual direct object class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

Line 22—Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

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

Attachment D

Assurances—Non-Construction Programs

Public reporting burden for this collection of information is estimated to average 15

minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regrading the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348–0040), Washington, DC 20503.

PLEASE DO NOT RETURN YOU COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

Note: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant, I certify that the applicant:

1. Has the legal authority to apply for Federal assistance and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project cost) to ensure proper planning, management and completion of the project described in this application.

2. Will give the awarding agency, the Comptroller General of the United States and, if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.

3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.

4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.

5. Will comply with the intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728–4763) relating to prescribed standards for merit systems for programs funded under one of the 19 statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900. Subpart F).

6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to (a) Title VI of the Civil Rights Act of 1964 (P.L. 88–352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681–1683, and 1685–1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§ 6101–6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92–255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91–616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. §§ 290 dd-3 and 290 ee 3), as amended, relating to confidentially of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. §§ 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statue(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.

7. Will comply, or has already complied, with the requirements of Title II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91–646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally-assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.

8. Will comply, as applicable, with provisions of the Hatch Act (5 U.S.C. §§ 1501–1508 and 7324–7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.

9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§ 276a to 276a–7), the Copeland Act (40 U.S.C. § 276c and 18 U.S.C. § 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 327–333), regarding labor standards for federally-assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93–234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.

11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91–190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clean Air) Implementation Plans under Section 176(c) of the Clean Air Act of 1955, as amended (42 U.S.C. §§ 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended (P.L. 93–523); and, (h) protection of endangered species under the Endangered Species Act of 1973, as amended (P.L. 93–205).

12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§ 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.

13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. § 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. §§ 469a–1 et seq.)

14. Will comply with P.L. 93–348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89–544, as amended, 7 U.S.C. §§ 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead-based paint in construction or rehabilitation of residence structures.

17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act Amendments of 1996 and OMB Circular No. A–133, ''Audits of States, Local Governments, and Non-Profit Organizations.''

18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL

TITLE

APPLICANT ORGANIZATION

DATE SUBMITTED

Attachment E

HHS CFR Title 45

PART 76, Appendix C: Drug-free Certification

Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements For Drug-Free Workplace (Grants)

Certification Regarding Drug-Free Workplace Requirements

Instructions for Certification

1. By signing and/or submitting this application or grant agreement, the grantee is providing the certification set out below.

2. The certification set out below is a material representation of fact upon which reliance is placed when the agency awards the grant. If it is later determined that the

grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, the agency, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free Workplace Act.

3. For grantees other than individuals, Alternate I applies.

4. For grantees who are individuals, Alternate II applies.

5. Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee's drug-free workplace requirements.

6. Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio studios).

7. If the workplace identified to the agency changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see paragraph five).

8. Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantees' attention is called, in particular, to the following definitions from these rules:

Controlled substance means a controlled substance in Schedules I through V of the Controlled Substances Act (21 U.S.C. 812) and as further defined by regulation (21 CFR 1308.11 through 1308.15);

Conviction means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

Criminal drug statute means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

Employee means the employee of a grantee directly engaged in the performance of work under a grant, including (i) All direct charge employees; (ii) All indirect charge employees unless their impact or involvement is insignificant to the performance of the grant; and, (iii) Temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee's payroll; or employees of subrecipients or subcontractors in covered workplace).

Certification Regarding Drug-Free Workplace Requirements

Alternate I. (Grantees Other Than Individuals)

1. The grantee certifies that it will or will continue to provide a drug-free workplace by:

1. Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;
2. Establishing an ongoing drug-free awareness program to inform employees about—
   1. The dangers of drug abuse in the workplace;
   2. The grantee's policy of maintaining a drug-free workplace;
   3. Any available drug counseling, rehabilitation, and employee assistance programs; and
   4. The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;
3. Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph(a);
4. Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will—
   1. Abide by the terms of the statement; and
   2. Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later that five calendar days after such conviction;
5. Notifying the agency in writing, within ten calendar days after receiving notice under paragraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;
6. Taking one of the following actions, within 30 calendar days of receiving notice under paragraph (d)(2), with respect to any employee who is so convicted—
   1. Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or
   2. Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;
7. Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraph (a), (b), (c), (d), (e) and (f).

2. The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant: Place of Performance (Street address, city, county, state, zip code) Check ☐ if there are workplaces on file that are not identified here.

Alternate II. (Grantees Who Are Individuals)

1. The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant;

2. If convicted of a criminal drug offense from a violation occurring during the conduct of any grant activity, he or she will report the conviction, in writing, within 10 calendar days of the conviction, to every grant officer or other designee, unless the Federal agency designates a central point for the receipt of such notices. When notice is made to such a central point, it shall include the identification number(s) of each affected grant.

(55 FR 21690, 21702, May 25, 1990)

Attachment F

HHS CFR Title 45

PART 76, Appendix A: Debarment Certification (Primary)

Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)

Certification Regarding Debarment, Suspension, and Other Responsibility Matters (Primary Covered Transactions)

Instructions for Certification

1. By signing and submitting this proposal, the prospective primary participant is providing the certification set out below.

2. The inability of a person to provide the certification required below will not necessarily result in denial of participation in this covered transaction. The prospective participant shall submit an explanation of why it cannot provide the certification set out below. The certification or explanation will be considered in connection with the department or agency's determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

3. The certification in this clause is a material representation of fact upon which reliance was placed when the department or agency determined to enter into this transaction. If it is the later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause of default.

4. The prospective primary participant shall provide immediate written notice to the department or agency to whom this proposal is submitted if at any time the prospective primary participant learns that its certification was erroneous when submitted

or has become erroneous by reason of changed circumstances.

5. The terms covered transacted, debarred, suspended, ineligible, lower tier covered transaction, participant, person, primary covered transaction, principal, proposal, and voluntary excluded, as used in this clause, have the meanings set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549. You may contact the department or agency to which this proposal is begin submitted for assistance in obtaining a copy of those regulations.

6. The prospective primary participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency entering into this transaction.

7. The prospective primary participant further agrees by submitting this proposal that it will include the clause titled ''Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transaction,'' provided by the department or agency entering into this covered transaction, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

8. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List (Tel. 1B).

9. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

10. Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntary excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions

1. The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:

1. Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by an Federal department or agency;
2. Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or contract under a public transaction, violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;
3. Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and
4. Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or local) terminated for cause or default.

2. Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Attachment G

State Single Point of Contact Listing Maintained by OMB

In accordance with Executive Order #12374, ''Intergovernmental Review of Federal Programs,'' Section 4, ''the Office of Management and Budget (OMB) shall maintain a list of official State entities designated by the State to review and coordinate proposed Federal financial assistance and direct Federal development.'' This attached listing is the OFFICIAL OMB LISTING. This listing is also published in the Catalogue of Federal Domestic Assistance biannually.

March 5, 1999.

OMB State Single Point of Contact Listing*

ARIZONA

Joni Saad, Arizona State Clearinghouse, 3800 N. Central Avenue, Fourteenth Floor, Phoenix, Arizona 85012, Telephone: (602) 280–1315; FAX: (602) 280–8144.

ARKANSAS

Mr. Tracy L. Copeland, Manager, State Clearinghouse, Office of Intergovernmental Service, Department of Finance and Administration, 515 W. 7th St., Room 412, Little Rock, Arkansas 72203, Telephone: (501) 682–1074; FAX: (501) 682–5206

CALIFORNIA

Grants Coordination, State Clearinghouse, Office of Planning & Research, 1400 Tenth Street, Room 121, Sacramento, California 95814, Telephone: (916) 445–0613; FAX: (916) 323–3018

DELAWARE

Francine Booth, State Single Point of Contact, Executive Department, Office of the Budget, 540 S. Dupont Highway, Suite 5, Dover, Delaware 19901, Telephone: (302) 739–3326; FAX: (302) 739–5661

DISTRICT OF COLUMBIA

Charles Nichols, State Single Point of Contact, Office of Grants Mgmt. & Dev., 717 14th Street, N.W. Suite 1200, Washington, D.C. 20005, Telephone: (202) 727–1700 (direct), (202) 727–6537 (secretary); FAX: (202) 727–1617

FLORIDA

Florida State Clearinghouse, Department of Community Affairs, 2555 Shumard Oak Blvd, Tallahassee, Florida 32399–2100, Telephone: (850) 922–5438, FAX: (850) 414–0479; Contact: Cherie Trainor, (850) 414–5495

GEORGIA

Deborah Stephens, Coordinator, Georgia State Clearinghouse, 270 Washington Street , S.W.—8th Floor, Atlanta, Georgia 30334, Telephone: (404) 656–3855; FAX: (404) 656–7901

ILLINOIS

Virginia Bova, State Single Point of Contact, Illinois Department of Commerce and Community Affairs, James R. Thompson Center, 100 West Randolph, Suite 3–400, Chicago, Illinois 60601, Telephone: (312) 814–6028, FAX: (312) 814–1800

INDIANA

Renee Miller, State Budget Agency, 212 State House, Indianapolis, Indiana 46204–2796, Telephone: (317) 232–2971 (directline); FAX: (317) 233–3323

IOWA

Steven R. McCann, Division of Community Assistance, Iowa Department of Economic Development, 200 East Grand Avenue, Des Moines, Iowa 50309, Telephone: (515) 242–4719; FAX: (515) 242–4809

KENTUCKY

Kevin J. Goldsmith, Director, Sandra Brewer, Executive Secretary, Intergovernmental Affairs, Office of the Governor, 700 Capitol Avenue, Frankfort, Kentucky 40601, Telephone: (502) 564–2611; FAX: (502) 564–0437

MAINE

Joyce Benson, State Planning Office, 184 State Street, 38 State House Station, Augusta, Maine 04333, Telephone: (207) 287–3261; FAX: (207) 287–6489

MARYLAND

Linda Janey, Manager, Plan & Project Review, Maryland Office of Planning, 301 W. Preston Street—Room 1104, Baltimore, Maryland 21201–2365, Staff Contact: Linda Janey, Telephone: (410) 767–4490; FAX: (410) 767–4480

MICHIGAN

Richard Pfaff, Southeast Michigan Council of Governments, 660 Plaza Drive—Suite 1900, Detroit, Michigan 48226, Telephone: (303) 961–4266; FAX: (313) 961–4869

MISSISSIPPI

Cathy Mallette, Clearinghouse Officer, Department of Finance and

Administration, 550 High Street, 303 Walters Sillers Building, Jackson, Mississippi 39201–3087, Telephone: (601) 359–6762; FAX: (601) 359–6758

MISSOURI

Lois Pohl, Federal Assistance Clearinghouse, Office of Administration, P.O. Box 809, Jefferson Building, 9th Floor, Jefferson City, Missouri 65102, Telephone: (314) 751–4834; FAX: (314) 751–7819

NEVADA

Department of Administration, State Clearinghouse, 209 E. Musser Street, Room 220, Carson City, Nevada 89710, Telephone: (702) 687–4065; FAX: (702) 687–3983; Contact: Heather Elliot, (702) 687–6367

NEW HAMPSHIRE

Jeffrey H. Taylor, Director, New Hampshire Office of State Planning, Attn: Intergovernmental Review Process, Mike Blake, 2½ Beacon Street, Concord, New Hampshire 03301, Telephone: (603) 271–2155; FAX: (603) 271–1728

NEW MEXICO

Nick Mandell, Local Government Division, Room 201 Bataan Memorial Building, Santa Fe, New Mexico 87503, Telephone: (505) 827–3640; FAX: (505) 827–4984

NEW YORK

New York State Clearinghouse, Division of the Budget, State Capitol, Albany, New York 12224, Telephone: (518) 474–1605; FAX: (518) 486–5617

NORTH CAROLINA

Jeanette Furney, North Carolina Department of Administration, 116 West Jones Street—Suite 5106, Raleigh, North Carolina 27603–8003, Telephone: (919) 733–7232; FAX: (919) 733–9571

NORTH DAKOTA

North Dakota Single Point of Contact, Office of Intergovernmental Assistance, 600 East Boulevard Avenue, Bismarck, North Dakota 58505–0170, Telephone: (701) 224–2094; FAX: (701) 224–2308

RHODE ISLAND

Kevin Nelson, Review Coordinator, Department of Administration, Division of Planning, One Capitol Hill, 4th Floor, Providence, Rhode Island 02908–5870, Telephone: (401) 277–2656; FAX: (401) 277–2083

SOUTH CAROLINA

Omeagia Burgess, State Single Point of Contact, Budget and Control Board, Office of State Budget, 1122 Ladies Street—12th Floor, Columbia, South Carolina 29201; Telephone: (803) 734–0494; FAX: (803) 734–0645

TEXAS

Tom Adams, Governors Office, Director, Intergovernmental Coordination, P.O. Box 12428, Austin, Texas 78711, Telephone: (512) 463–1771; FAX: (512) 463–2681

UTAH

Carolyn Wright, Utah State Clearinghouse, Office of Planning and Budget, Room 116 State Capitol, Salt Lake City, Utah 84114; Telephone: (801) 538–1027; FAX: (801) 538–1547

WEST VIRGINIA

Fred Cutlip, Director, Community Development Division, W. Virginia Development Office, Building #6, Room 553, Charleston, West Virginia 25305, Telephone: (304) 558–4010; FAX: (304) 558–3248

WISCONSIN

Jeff Smith, Section Chief, Federal/State Relations, Wisconsin Department of Administration, 101 East Wilson Street—6th Floor, P.O. Box 7868, Madison, Wisconsin 53707, Telephone: (608) 266–0267; FAX: (608) 267–6931

WYOMING

Sandy Ross, State Single Point of Contact, Department of Administration and Information, 2001 Capitol Avenue, Room 214, Cheyenne, Wyoming 82002, Telephone: (307) 777–5492; FAX: (307) 777–3696

TERRITORIES

GUAM

Joseph Rivera, Acting Director, Bureau of Budget and Management Research, Office of the Governor, P.O. Box 2950, Agana, Guam 96932, Telephone: (617) 475–9411 or 9412; FAX: (671) 472–2825

PUERTO RICO

Jose Caballero-Mercado, Chairman, Puerto Rico Planning Board, Federal Proposals Review Office, Minillas Government Center, P.O. Box 41119, San Juan, Puerto Rico 00940–1119, Telephone: (787) 727–4444, (787) 723–6190; FAX: (787) 724–3270

NORTH MARIANA ISLANDS

Mr. Alvaro A. Santos, Executive Officer, Office of Management and Budget, Office of the Governor, Saipan, MP 96950, Telephone: (670) 664–2256; FAX: (670) 664–2272; Contact person: Ms. Jacoba T. Seman, Federal Programs Coordinator, Telephone: (670) 664–2289; FAX: (670) 664–2272

VIRGIN ISLANDS

Nellon Bowry, Director, Office of Management and Budget, #41 Norregade Emancipation Garden Station; Second Floor; Saint Thomas, Virgin Islands 00802

Please direct all questions and correspondence about intergovernmental review to: Linda Clarke, Telephone: (809) 774–0750; FAX: (809) 776–0069

If you would like a copy of this list faxed to your office, please call our publications office at (202) 395–9068

* In accordance with Executive Order #12372, ''Intergovernmental Review of Federal Programs,'' this listing represents the designated State Single Points of Contact. The jurisdictions not listed no longer participate in the process, BUT GRANT APPLICANTS ARE STILL ELIGIBLE TO APPLY FOR THE GRANT EVEN IF YOUR STATE, TERRITORY, COMMONWEALTH, ETC., DOES NOT HAVE A ''STATE SINGLE POINT OF CONTACT.'' STATES WITHOUT ''STATE SINGLE POINTS OF CONTACT'' INCLUDE: Alabama; Alaska; American Samoa; Colorado; Connecticut; Hawaii; Idaho; Kansas; Louisiana; Massachusetts; Minnesota; Montana; Nebraska; New Jersey; Ohio; Oklahoma; Oregon; Palau; Pennsylvania; South Dakota; Tennessee; Vermont; Virginia; and Washington. This list is based on the most current information provided by the States. Information on any changes or apparent errors should be provided to the Office of Management and Budget and the State in question. Changes to the list will only be made upon formal notification by the State. Also, this listing is published biannually in the Catalogue of Federal Domestic Assistance.

Attachment H

Developing ACF Program Announcements

CERTIFICATION REGARDING LOBBYING

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, ''Disclosure Form to Report Lobbying,'' in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly. This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Statement for Loan Guarantees and Loan Insurance.

The undersigned states, to the best of his or her knowledge and belief, that:

If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States of insure or guarantee a loan, the undersigned shall complete and submit Standard Form-LLL, ''Disclosure Form to Report Lobbying,'' in accordance with its instructions. Submission of this statement is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required statement shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

_____

Signature

_____

Title

_____

Organization

_____

Date

BILLING CODE 4184–01–P

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB 0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action: ☐ a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	**2. Status of Federal Action:** ☐ a. bid/offer/application b. initial award c. post-award	**3. Report Type:** ☐ a. initial filing b. material change **For Material Change Only:** year _____ quarter _____ date of last report _____
4. Name and Address of Reporting Entity: ☐ **Prime** ☐ **Subawardee** Tier _____, *if known*: **Congressional District**, *if known*:	**5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime:** **Congressional District**, *if known*:	
6. Federal Department/Agency:	**7. Federal Program Name/Description:** CFDA Number, *if applicable*: _____	
8. Federal Action Number, *if known*:	**9. Award Amount**, *if known*: $	
10. a. Name and Address of Lobbying Registrant (*if individual, last name, first name, MI*):	**b. Individuals Performing Services** (*including address if different from No. 10a*) (*last name, first name, MI*):	
11. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less that $10,000 and not more than $100,000 for each such failure.	Signature: _____ Print Name: _____ Title: _____ Telephone No.: _____ Date: _____	
Federal Use Only:		Authorized for Local Reproduction Standard Form LLL (Rev. 7-97)

BILLING CODE 4184–01–C

Attachment H (Page 3)

INSTRUCTIONS FOR COMPLETION OF SF–LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks ''Subawardee,'' then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., ''RFP–DE–90–001.''

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, State and zip code of the lobbying registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

(b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a). Enter Last Name, First Name, and Middle Initial (MI).

11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

According to the Paperwork Reduction Act, as amended, no persons are required to respond to a collection of information unless if displays a valid OMB Control Number. The valid OMB control number for this information collection is OMB No. 0348–0046. Public reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management Budget, Paperwork Reduction Project (0348–0046), Washington, DC 20503.

Attachment I

Department of Health and Human Services (DHHS) Regulations Applying to All Applicants/Grantees Under The Fiscal Year 2000 Discretionary Grants Program

Title 45 of the Code of Federal Regulations

Part 16—DHHS Grant Appeals Process
Part 74—Administration of Grants (non-governmental)
Part 74—Administration of Grants (state and local governments and Indian Tribal affiliates):
Sections
74.26 Non-Federal Audits
74.27 Allowable cost for hospitals and non-profit organizations among other things
74.32 Real Property
74.34 Equipment
74.35 Supplies
74.24 Program Income
Part 75—Informal Grant Appeal Procedures
Part 76—Debarment and Suspension from Eligibility For Financial Assistance

Subpart F—Drug Free Workplace Requirements

Part 80—Non-discrimination Under Programs Receiving Federal Assistance through DHHS Effectuation of Title VI of the Civil Rights Act of 1964
Part 81—Practice and Procedures for Hearings Under Part 80 of this title
Part 83—Regulation for the Administration and Enforcement of Sections 799A and 845 of the Public Health Service Act
Part 84—Non-discrimination on the Basis of Handicap in Programs and Activities Receiving Federal Financial Assistance
Part 85—Enforcement of Non-discrimination on the Basis of Handicap in Programs or Activities Conducted by DHHS
Part 86—Non-discrimination on the Basis of Sex in Education Programs and Activities Receiving or Benefiting from Federal Financial Assistance
Part 91—Non-discrimination on the Basis of Age in Health and Human Services Programs or Activities Receiving Federal Financial Assistance
Part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to States and Local Governments (Federal Register, March 11, 1988)
Part 93—New Restrictions on Lobbying
Part 100—Intergovernmental Review of DHHS Programs and Activities

Attachment J

Certification Regarding Environmental Tobacco Smoke

Public Law 103227, Part C Environmental Tobacco Smoke, also known as the Pro Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor routinely owned or leased or contracted for by an entity and used routinely or regularly for provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1000 per day and/or the imposition of an administrative compliance order on the responsible entity. By signing and submitting this application the applicant/grantee certifies that it will comply with the requirements of the Act.

The applicant/grantee further agrees that it will require the language of this certification be included in any subawards which contain provisions for the children's services and that all subgrantees shall certify accordingly.

Attachment K

Guidelines for a Business Plan

The application must contain a detailed and specific workplan or business plan that is both sound and feasible. Generally, a business plan is required for applications submitted under sub-priority areas 1.1, 1.2 and 1.4. For all business ventures (except for business development opportunities for self-employed program participants) a complete business plan will be required using guidelines discussed in the next several paragraphs. For the remaining sub-priority areas, a workplan is acceptable in lieu of a business plan.

Please note that OCS does not require the application to contain business plans for each self-employed program participant. However, a project that proposes to provide self-employed and other business opportunities for program participants must

include a development plan that shows how participants will become self-sufficient and how their technical assistance needs will be met.

Guidelines of a Business Plan

The business plan is one of the major components that will be evaluated by the OCS to determine the feasibility of a business venture or an economic development project. It must be well prepared and address all the relevant elements as follows:

(a) EXECUTIVE SUMMARY (limit summary to 3 pages)

(b) *The business and its industry*. This section should describe the nature and history of the business and provide some background on its industry.

(i) *The Business*: as a legal entity; the general business category;

(ii) *Description and Discussion of Industry*: current status and prospects for the industry;

(c) *Products and Services*: This section deals with the following:

(i) *Description*: Describe in detail the products or services to be sold;

(ii) *Proprietary Position*: Describe proprietary features if any of the product, e.g., patients, trade secrets;

(iii) *Potential*: Features of the product or service that may give it an advantage over the competition;

(d) *Market Research and Evaluation*: The applicant should consider businesses in growth industries and occupations with skill levels accessible to low income persons. Businesses should be identified by Standard Industrial Codes (SIC) and jobs by occupational classifications. This information is published by the U.S. Department of Commerce in the ''Statistical Abstract of the United States, 1996'', Table No. 646 and 647. Also, you may use the table included as ''Attachment L'' to identify industrial areas and occupational classifications. This section should present sufficient information to show that the product or service has a substantial market and can achieve sales in the face of competition;

(i) *Customers*: Describe the actual and potential purchasers for the product or service by market segment.

(ii) *Market Size and Trends*: State the site of the current total market for the product or service offered;

(iii) *Competition*: An assessment of the strengths and weaknesses of competition in the current market;

(iv) *Estimated Market Share and Sales*: Describe the characteristics of the product or service that will make it competitive in the current market;

(e) *Marketing Plan*: The marketing plan should detail the product, pricing, distribution, and promotion strategies that will be used to achieve the estimated market share and sales projections. The marketing plan must describe what is to be done, how it will be done and who will do it. The plan should address the following topics—Overall Marketing Strategy, Packaging, Service and Warranty, Pricing, Distribution and Promotion.

(f) *Design and Development Plans*: If the product, process or service of the proposed venture requires any design and development before it is ready to be placed on the market, the nature and extent and cost of this work should be fully discussed. The section should cover items such as Development Status and Tasks, Difficulties and Risks, Product Improvement and New Products, and Costs.

(g) *Manufacturing and Operations Plan*: A manufacturing and operations plan should describe the kind of facilities, plant location, space, capital equipment and labor force (part and/or full time and wage structure) that are required to provide the company's product or service.

(h) *Management Team:* The management team is the key in starting and operating a successful business. The management team should be committed with a proper balance of technical, managerial and business skills, and experience in doing what is proposed. This section must include a description of: the key management personnel and their primary duties; compensation and/or ownership; the organizational structure; Board of Directors; management assistance and training needs; and supporting professional services.

(i) *Overall Schedule:* A schedule that shows the timing and interrelationships of the major events necessary to launch the venture and realize its objectives. Prepare, as part of this section, a month-by-month schedule that shows the timing of such activities as product development, market planning, sales programs, and production and operations. Sufficient detail should be included to show the timing of the primary tasks required to accomplish each activity.

(j) *Critical Risks and Assumptions:* The development of a business has risks and problems and the Business Plan should contain some explicit assumptions about them. Accordingly, identify and discuss the critical assumptions in the Business Plan and the major problems that will have to be solved to develop the venture. This should include a description of the risks and critical assumptions relating to the industry, the venture, its personnel, the products market appeal, and the timing and financing of the venture.

Also, if a ''construction project'' is involved, the Business Plan should identify and address briefly the project's timeframes and critical assumptions for conduct of predevelopment, architectural/engineering and environmental studies, etc., and acquisition of permits for building, use and occupancy that are required for the project.

(k) *Community Benefits:* The proposed project must contribute to economic, human and community development within the projects targets area. A section that describes and discusses the potential economic and non-economic benefits to low income members of the community must be included as well as a description of the strategy that will be used to identify and hire individuals being served by public assistance programs and how linkages with community agencies/organizations administering the AFDC/TANF program will be developed. The following project benefits must be described:

Economic Development and Job Creation

Number of permanent jobs (with particular emphasis on jobs for low-income people) that will be created during the project period. Also, for low-income people, provide the following information:

—Number of jobs that will have career development opportunities and a description of those jobs;
—Number of jobs that will be filled by individuals lifted from AFDC/TANF assistance;
—Number of Self-employed and other ownership opportunities created for low-income residents;
—Annual salary expected for each person employed (net profit after deductions of business expenses for self-employed persons);
—Specific steps to be taken including on-going management support and technical assistance provided by the grantee or a third party to develop and sustain self-employed program participants after their businesses are in place.

Note: OCS will not recognize job equivalents nor job counts based on economic multiplier functions; jobs must be specifically identified.

Other benefits, which might be discussed, are:

Human Development

—New technical skills development and associated career opportunities for community residents;
—Management development and training;
—Benefits of self-sufficient for persons lifted from AFDC/TANF assistance.

Community Development

—Development of community's physical assets;
—Provision of needed, but currently unsupplied, services or products to community;
—Improvement in the living environment.

(1) *The Financial Plan:* The Financial Plan is basic to the development of a Business Plan. Its purpose is to indicate the project's potential and the timetable for financial self-sufficiency. In developing the Financial Plan, the following exhibits must be prepared for the first three years of the business' operation:

(i) Profit and Loss Forecasts—quarterly for each year.

(ii) Cash Flow Projections—quarterly for each year.

(iii) Pro forma balance sheets—quarterly for each year.

Also, additional financial information for the business operation that must be included are an initial Source and Use of Funds Statement for project funds and a brief summary paragraph discussing any further capital requirements and their sources.

If an applicant is proposing a project which will affect a property listed in, or eligible for inclusion in the National Register of Historic Places, it must identify this property in the narrative and explain how it complied with the provisions of Section 106 of the National Historic Preservation Act of 1966 as amended. If there is any question as to

whether the property is listed in or eligible for inclusion in the National Register of Historic Places, the applicant should consult with the Senate Historic Preservation Officer. (See Attachment D: SF–42B, Item 13 for additional guidance.) The applicant should contact OCS early in the development of its application for instructions regarding compliance with the Act and data required to be submitted to the Department of Health and Human Services. Failure to comply with the cited Act may result in the application being ineligible for funding consideration.

Applicable to Sub-Priority Areas 1.1, 1.2, and 1.4

Applications submitted under Sub-Priority Areas 1.1, 1.2 and 1.4 which propose to use the requested OCS funds to make an equity investment or a loan to a business concern, including a wholly-owned subsidiary, or to make a sub-grant with a portion of OCS funds, must include a written agreement between the community development corporation and the recipient of the grant funds which contains all of the elements listed in Part C under the appropriate Priority Area.

Applicable to Sub-Priority Area 1.5 Only

An applicant in this priority area must document its experience and capability in several of the following areas:

—Business/Development;
—Micro-Entrepreneurship Development;
—Commercial Development;
—Organizational and Staff Development;
—Board Training;
—Business Management, including Strategic Planning and Fiscal Management;
—Finance, including Business Packaging and Financial/Accounting Services, and/or;
—Regulatory compliance including Zoning and permit Compliance;
—Incubator Development;
—Tax Credits and Bond Financing;
—Marketing.

The applicant must document staff competence or the accessibility of third party resources with proven competence. If the work program requires the significant use of third party (consultant/contractor) resources, those resources should be identified and resumes of the individuals or key organizational staff provided.

Résumés of the applicant's staff, who are to be directly involved in programmatic and administrative expertise sharing, should also be included. The applicant must document successful experience in the mobilization of resources (both cash and in-kind) from private and public sources. The applicant must also clearly state how the information learned from this project may be disseminated to other interested grantees.

Applicable to Sub-Priority Area 1.6 Only

An applicant in this priority area must document its experience and capability in implementing projects national in scope and have significant and relative experiences in working with community development corporations.

The applicant must have the ability to collect and analyze data nationally that may benefit CDCs and be able to disseminate information to all of OCS funding grantees; publish a national directory of funding sources for CDCs (public, corporate, foundation, religious); publish research papers on specific aspects of job creation by CDCs; design and provide information on successful projects and economic niches that CDCs can target. The applicant will also be responsible for the development of instructional programs, national conferences, seminars, and other activities to assist community development corporations; and provide peer-to-peer technical assistance to OCS funded CDCs.

Applicable to Sub-Priority Area 2.1

Each applicant must include a full discussion of how the proposed use of funds will enable low-income rural communities to develop the capability and expertise to establish and maintain affordable, adequate and safe water and waste water systems. Applicants must also discuss how they will disseminate information about water and waste water programs serving rural communities, and how they will better coordinate Federal, State, and local water and waste water program financing and development to assure improved service to rural communities.

Among the benefits that merit discussion under this sub-priority area are: The number of rural communities to be provided with technical and advisory services; the number of rural poor individuals who are expected to be directly served by applicant-supported improved water and waste water systems; the decrease in the number of inadequate water systems related to applicant activity; the number of newly-established and applicant-supported treatment systems (all of the above may be expressed in terms of equivalent connection units); the increase in local capacity in engineering and other areas of expertise; and the amount of non-discretionary program dollars expected to be mobilized.

e. Significant and Beneficial Impact and Other Criteria

The project narrative must address the remaining aspects of the project noted in the outline of Part F, ''Contents of Application and Receipt Process'', Items V and VI. These include private partnerships and Budget Appropriateness and Reasonableness'' areas as well as information to be included in the appendices.

Attachment L

TABLE OF STANDARD INDUSTRIAL CODES AND OCCUPATIONAL CLASSIFICATIONS

Standard industrial (sic) codes	Occupational classifications
Agriculture Mining Construction Manufacturing Transportation, and Public Utilities Wholesale and Retail Trade Finance, Insurance and Real Estate Services Government	Managerial and Professional Specialty Technical sales, and Administrative support (includes technicians and related support, technicians, sales occupations, including clerical). Precision Production, Craft, and Repair (includes mechanics, repairers, construction trades, crafters). Operators, fabricators, and laborers (includes machine operators, assemblers, inspectors, transportation and material moving occupations, handlers, equip cleaners, Helpers, laborers including construction laborers). Farming, Forestry and Fishing.

Source: U.S. Department of Commerce, ''Statistical Abstract of the United States, 1996'', Table No. 646 and 647. Updated 1998. Table No. 679 and 680.

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Attachment M

APPLICANT'S CHECKLIST

This checklist will assist you with preparing and assembling your application. Completing the checklist can help ensure that you do not omit key information. Because this checklist is used by many ACF programs, some of the information might not apply to your application. This checklist DOES NOT have to be completed and returned with your application.

	Yes	Included	N/A
Authorizing official read and understood Certification Regarding Debarment, Suspension, and Other Responsibility Matters?			
Authorizing official read and understood Certification Regarding Drug-Free Workplace Requirements--Grantees Other Than Individuals?			
Authorizing official read and understood Certification Regarding Environmental Tobacco Smoke?			
Application for Federal Assistance (SF 424) was completed? Proper Signature and Date for Line 18?			
Budget Information--Non-Construction Programs (SF 424A) or Budget Information--Construction Programs (SF 424C) was completed?			
Assurances-- Non-Construction Programs (SF 424B) or Assurances--Construction Programs (SF 424D) was completed? (Proper Signature and Date?)			
Certification Regarding Lobbying was completed? (Proper Signature and Date?)			
Disclosure of Lobbying Activities was completed? (Proper Signature and Date?)			
Other special certifications, assurances, and/or disclosures required under the program were completed (e.g., maintenance of effort certification)?			
Proof of nonprofit status was provided?			
Has additional information such as biographical sketch(es) with job description(s) and other additional information been attached, when required?			
For a Supplemental application, does the detailed budget only address the additional funds requested?			
Checked all budget computations for accuracy?			

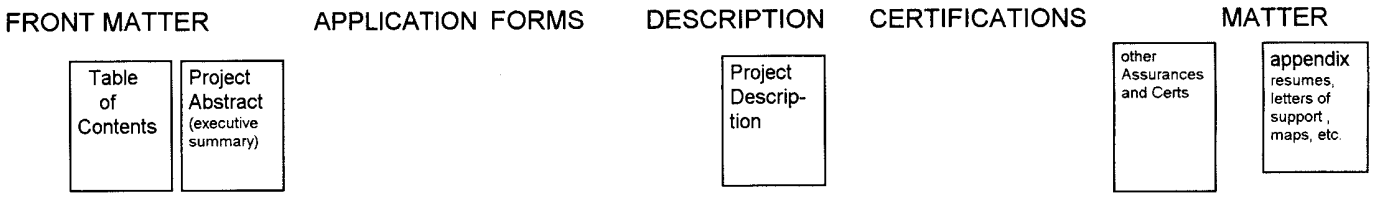
FOLLOW-UP QUESTIONS

	YES	N/A
On the Application for Federal Assistance (SF 424),		
⇒ did you enter the application number issued by the sponsoring ACF office in the "Federal Identifier" block?		
⇒ did you type the 12 digit Payee EIN or PIN previously assigned to your organization by DHHS in the "Federal Identifier" block?		
⇒ is the EIN in Item #6 assigned to the organization and organizational unit named in Item #5?		
⇒ did you include city, county, state and zip code of the applicant did organization in Item #5?		
⇒ has the appropriate box been checked in Item #16?		
⇒ has the entire proposed project period been identified in Item #13?		
On the Budget Information form (SF 424A or SF 424C),		
⇒ do the totals in Section B match the totals provided in the budget and budget narrative?		

SUGGESTED ORDERING OF APPLICATION MATERIALS

	STANDARD			PROJECT	DISCLOSURES		END
COVER LETTER	SF 424	SF 424A or SF 424C	SF 424B or SF 424D		Certification regarding lobbying	Disclosure of lobbying activities	

Attachment M (Page 2)



[FR Doc. 99–21355 Filed 8–18–99; 8:45 am]

BILLING CODE 4184–01–C

federal register

Thursday
August 19, 1999

Part III

Department of Transportation

Federal Aviation Administration

14 CFR Part 29

Airworthiness Standards; Transport Category Rotorcraft Performance; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 29

[Docket No. 24802; Amendment No. 29–44]

RIN 2120–AG86

Airworthiness Standards; Transport Category Rotorcraft Performance

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This rule amends the airworthiness standards for Transport Category rotorcraft by making several nonsubstantive clarification changes to the wording and by correcting various nonsubstantive errors in the performance requirements section. This rule is needed to correct errors in a final rule published on May 10, 1996.

DATES: This final rule is effective November 17, 1999. Comments must be submitted on or before September 20, 1999.

ADDRESSES: Submit comments in duplicate to the Federal Aviation Administration, Office of the Chief Counsel (AGC–200), Attention: Rules Docket No. 24802, 800 Independence Ave., SW, Washington, DC 20591.

Comments may also be submitted electronically to the following Internet address: 9–NPRM–CMTS@faa.gov. Comments submitted must be marked: Docket No. 24802.

Comments may be examined in Room 915G on weekdays between 8:30 a.m. and 5:00 p.m., except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lance T. Gant, Rotorcraft Standards Staff, Aircraft Certification Service, Federal Aviation Administration, Fort Worth, Texas 76193–0110, telephone (817) 222–5114, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION:

Comments Invited

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

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 24802.'' The postcard will be date stamped and returned to the commenter.

Availability of Final Rule

Any person may obtain a copy of this final rule by submitting a request to: FAA, Office of Rulemaking, Attention: ARM–1, 800 Independence Avenue, SW., Washington, DC 20591; or by telephoning (202) 267–9680. Individuals requesting a copy of this final rule should identify their request with the amendment number or docket number.

An electronic copy of this final rule may be downloaded, by using a modern and suitable communications software, from: the FAA regulations section of the FedWorld electronic bulletin board service (telephone: (703) 321–3339); the Government Printing Office's electronic bulletin board service (telephone (202) 512–1661); or the FAA's Aviation Rulemaking Advisory Committee Bulletin Board service (telephone: (202) 267–5948).

Internet users may reach the FAA's web page at http://www.faa.gov, or the Government Printing Office's webpage at http://www.access.gpo.gov/nara, for access to recently published rulemaking documents.

Small Entity Inquiries

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBEFA) requires the FAA to report inquiries from small entities concerning information on, and advice about, compliance with statutes and regulations within the FAA's jurisdiction, including interpretation and application of the law to specific sets of facts supplied by a small entity.

If you are a small entity and have a question, contact your local FAA official, you may contact Charlene Brown, Program Analyst Staff, Office of Rulemaking, ARM–27, Federal Aviation Administration, 800 Independence Avenue, SW, Washington, DC 20591, 1–888–551–1594. Internet users can find additional information on SBREFA in the ''Quick Jump'' section under ''Rulemaking'' of the FAA's web page at http://www.faa.gov and may send electronic inquiries to the following internet address: 9–AWA–SBREFA@faa.gov.

Background

After publication of the Transport Category Rotocraft Notice of Proposed Rulemaking (NPRM), Notice 90–1 (55 FR 698, January 8, 1990), the Joint Harmonization Working Group (JHWG) proposed some nonsubstantive changes to be included in the final rule. The FAA reviewed the JHWG proposal and concurred with the changes. However, the changes were inadvertently omitted in the final rule published May 10, 1996 (61 FR 21894), and two correction documents published July 1, 1996 (61 FR 33963), and July 15, 1996 (61 FR 36965), following Notice 90–1.

This final rule will make the nonsubstantive changes to some paragraphs of part 29. The changes will clarify the language to avoid confusion and diverse interpretations of these standards.

Discussion

The following is a discussion of the changes of part 29:

14 CFR 29.59 Takeoff Path: Category A

Section 29.59 is revised for clarification. The revision is an editorial reordering of paragraphs.

14 CFR 29.62 Rejected Takeoff: Category A

Section 29.62(a) is revised for clarification. The current wording of § 29.62(a) may be interpreted to imply that the procedures of §§ 29.59 and 29.60 are to be followed only to the engine failure point and that the takeoff and rejected takeoff paths may diverge from that point. However, in calculating the rejected takeoff path distances of § 29.62(a), the requirements of §§ 29.59 and 29.60 are to be followed up to the takeoff decision point (TDP). Therefore, the section is revised by removing references to the engine failure point to preclude misinterpretation of the requirement.

14 CFR 29.67 Climb: One-Engine-Inoperative (OEI)

In § 29.67, the introductory text of paragraph (a)(2), paragraphs (a)(2)(i) and (a)(3)(i), and the introductory text of paragraph (b) are revised to specify that the engine power ratings are for one-engine inoperative to be consistent with § 29.1521. Paragraph (a)(2)(ii) is deleted because the requirement is previously stated in § 29.64. The deletion of paragraph (a)(2)(ii) resulted in an editorial renumbering of paragraphs (iii) and (iv) as (ii) and (iii) respectively.

14 CFR 29.77 Landing Decision Point (LDP): Category A

The requirements of § 29.77 are clarified by dividing this section into paragraphs (a) and (b) and clearly identifying the inclusion of the pilot recognition time interval in the definition of the LDP.

14 CFR 29.81 Landing Distance: Category A

In § 29.81, the requirement to determine landing distance from a height of 25 feet for elevated landing operations is deleted. The requirement to determine landing distance from 25 feet has no operational significance and represents an unnecessary consideration for elevated heliports.

14 CFR 29.85 Balked Landing: Category A

Editorial changes in § 29.85 insert the phrase ''with the critical engine inoperative'' in the introductory text and delete that phrase from paragraph (a) and a similar phrase from paragraph (b). In paragraph (c), the word ''distance'' is replaced with the more descriptive term ''(loss of height)''.

14 CFR 29.1323 Airspeed Indicating System

In § 29.1323(c)(1), an editorial correction changes ''critical'' decision point to read ''takeoff'' decision point. This term parallels the term used in other sections of part 29.

14 CFR 29.1587 Performance Information

In § 29.1587(a)(4) and (5), references to §§ 29.63 and 29.83 are deleted because those sections are applicable to Category B performance, and § 29.1587(a) contains only Category A requirements. Additionally, reference to § 29.85, omitted in error, is added to paragraph (a)(5).

Paperwork Reduction Act

In accordance with the paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), there are no reporting or recordkeeping requirements associated with this final rule.

Agency Findings

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

The FAA has determined that notice and prior public comment are unnecessary in promulgating this regulation. Therefore, it can be issued immediately since it only involves minor correction, clarification, and editorial changes. For the reasons discussed in the preamble, I certify that this regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

International Traded Impact Statement

The rule will not constitute a barrier to international trade, including the export of U.S. goods and services to foreign countries and the import of foreign goods and services into the United States.

Unfunded Mandates Reform Act Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (the Act), codified as 2 U.S.C. §§ 1501–1571, requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency rule that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million or more (adjusted annually for inflation) in any one year.

This rule does not meet the thresholds of the Act. Therefore, the requirements of Title II of the Act do not apply.

Environmental Analysis

FAA Order 1050.1D defines FAA actions that may be categorically excluded from preparation of a National Environmental Policy Act (NEPA) environmental assessment or environmental impact statement. In accordance with FAA Order 1050.1D, appendix 4, paragraph 4(j), this rulemaking action qualifies for a categorical exclusion.

Energy Impact

The energy impact of this rulemaking has been assessed in accordance with the Energy Policy and Conservation Act (EPCA) and Public Law 94–163, as amended (42 U.S.C. 6362). It has been determined that it is not a major regulatory action under the provisions of the EPCA.

List of Subjects in 14 CFR Part 29

Air transportation, Aircraft, Aviation safety, Rotorcraft, Safety.

The Amendment

Accordingly, the Federal Aviation Administration amends 14 CFR part 29 of the Federal Aviation Regulation as follows:

PART 29—AIRWORTHINESS STANDARDS: TRANSPORT CATEGORY ROTORCRAFT

1. The authority citation for part 29 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44704.

2. In § 29.59, paragraph (e) is redesignated as paragraph (c), and paragraphs (c) and (d) are redesignated as (d) and (e) respectively.

3. Section 29.62(a) is revised to read as follows:

§ 29.62 Rejected takeoff: Category A

* * * * *

(a) The takeoff path requirements of §§ 29.59 and 29.60 being used up to the TDP where the critical engine failure is recognized and the rotorcraft is landed and brought to a complete stop on the takeoff surface;

* * * * *

4. Secti8on 29.67 is amended by revising the introductory text of paragraph (a)(2), paragraphs (a)(2)(i) and (a)(3)(i), and paragraph (b); by removing paragraph (a)(2)(ii); and by redesignating (a)(2)(iii) and (a)(2)(iv) as (a)(2)(ii) and (a)(2)(iii) respectively.

§ 29.67 Climb: One-engine-inoperative (OEI)

(a) * * *

(2) The steady rate of climb without ground effect, 1000 feet above the

takeoff surface, must be at least 150 feet per minute, for each weight, altitude, and temperature for which takeoff data are to be scheduled with—

(i) The critical engine inoperative and the remaining engines at maximum continuous power including continuous OEI power, if approved, or at 30-minute OEI power for rotorcraft for which certification for use of 30-minute OEI power is requested;

* * * * *

(3) * * *

(i) The critical engine operative and the remaining engines at maximum continuous power including continuous OEI power, if approved, and at 30-minute OEI power for rotorcraft for which certification for the use of 30-minute OEI power is requested;

* * * * *

(b) For multiengine Category B rotorcraft meeting the Category A engine isolation requirements, the steady rate of climb (or descent) must be determined at the speed for best rate of climb (or minimum rate of descent) at each altitude, temperature, and weight at which the rotorcraft is expected to operate, with the critical engine inoperative and the remaining engines at maximum continuous power including continuous OEI power, if approved, and at 30-minute OEI power for rotorcraft for which certification for the use of 30-minute OEI power is requested.

5. Section 29.77 is revised to read as follows:

§ 29.77 Landing decision Point (LDP): Category A

(a) The LDP is the last point in the approach and landing path from which a balked landing can be accomplished in accordance with § 29.85.

(b) Determination of the LDP must include the pilot recognition time interval following failure of the critical engine.

6. Section 29.81 is revised to read as follows:

§ 29.81 Landing distance: Category A.

The horizontal distance required to land and come to a complete stop (or to a speed of approximately 3 knots for water landings) from a point 50 ft above the landing surface must be determined from the approach and landing paths established in accordance with § 29.79.

7. Section 29.85 is revised to read as follows:

§ 29.85 Balked landing: Category A.

For Category A rotorcraft, the balked landing path with the critical engine inoperative must be established so that—

(a) The transition from each stage of the maneuver to the next stage can be made smoothly and safely;

(b) From the LDP on the approach path selected by the applicant, a safe climbout can be made at speeds allowing compliance with the climb requirements of § 29.67(a)(1) and (2); and

(c) The rotorcraft does not descend below 15 feet above the landing surface. For elevated heliport operations, descent may be below the level of the landing surface provided the deck edge clearance of § 29.60 is maintained and the descent (loss of height) below the landing surface is determined.

§ 29.1323 [Amended]

8. In Section 29.1323(c)(1), the word ''critical'' is removed and add the word ''takeoff' in its place.

§ 29.1587 [Amended]

9. In § 29.1587(a)(4), remove the words ''or § 29.63'',

10. In § 29.1587(a)(5), remove the words ''or § 29.83'' and add the words ''and § 29.85'' in their place.

Issued in Washington, DC, on August 12, 1999.

Jane F. Garvey,

Administrator.

[FR Doc. 99–21380 Filed 8–18–99; 8:45 am]

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federal register

Thursday
August 19, 1999

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 600 et al.

Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents and Requirements for Blood, Blood Components, and Blood Derivatives; Rules and Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 607, 610, 640, and 660

[Docket No. 98N–0581]

Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise the general biological product standards by updating the hepatitis B virus (HBV) and human immunodeficiency virus (HIV) testing requirements, by adding testing requirements for hepatitis C virus (HCV), human T-lymphotropic virus (HTLV), and by adding requirements for licensed supplemental (i.e., additional, more specific) testing when a donation is found to be repeatedly reactive for any of the required screening tests for evidence of infection due to communicable disease agents. The agency is also proposing to require manufacturers of test kits approved for use in testing donations of human blood and blood components for evidence of infection due to communicable disease agents to use reference panels, when available, to verify the acceptable sensitivity and specificity of each lot. FDA is taking this action as part of the agency's ''Blood Initiative'' in which FDA is reviewing and revising, when appropriate, its regulations, policies, guidance, and procedures related to blood and blood products, including plasma derivatives. This proposed rule is intended to help protect the safety and ensure the quality of the nation's blood supply and to promote consistency in the industry.

DATES: Submit written comments on the proposed rule by November 17, 1999. Submit written comments on the information collection provisions by September 20, 1999. The agency is proposing that any final rule that may issue based upon this proposed rule become effective 180 days after its date of publication in the **Federal Register**.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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., Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. The Blood Initiative

For a variety of reasons, discussed as follows, FDA has decided to comprehensively review and, as necessary, revise its regulations, policies, guidance, and procedures related to the licensing and regulation of blood products. In the **Federal Register** of June 3, 1994 (59 FR 28821 and 59 FR 28822, respectively), FDA issued two documents entitled ''Review of General Biologics and Licensing Regulations'' (Docket No. 94N–0066) and ''Review of Regulations for Blood Establishments and Blood Products'' (Docket No. 94N–0080). The documents announced the agency's intent to review biologics regulations in parts 600, 601, 606, 607, 610, 640, and 660 (21 CFR parts 600, 601, 606, 607, 610, 640, and 660) and requested written comments from the public. Interested persons were given until August 17, 1994, to respond to the documents. In response to requests for additional time, FDA twice extended the comment period, as announced in the **Federal Register** of August 17, 1994 (59 FR 42193), and November 14, 1994 (59 FR 56448). In addition, FDA responded to requests for a public meeting to allow for the presentation of comments regarding the agency's intent to review the biologics regulations. On January 26, 1995, FDA held a public meeting to provide an opportunity for all interested individuals to present their comments and to assist the agency in determining whether the regulations should be revised, rescinded, or continued without change. Since the time of the regulation review, FDA has implemented a number of changes to its regulations and policies applicable to the general biologics and licensing regulations, some of which applied to blood products as well as other biological products. (See, e.g., the final rules issued on May 14, 1996 (61 FR 24313); August 1, 1996 (61 FR 40153); November 6, 1996 (61 FR 57328); July 24, 1997 (62 FR 39890); and October 15, 1997 (62 FR 53536).)

Because of the importance of a safe national blood supply, the U.S. House of Representatives Committee on Government Reform and Oversight, Subcommittee on Human Resources and Intergovernmental Relations (the Subcommittee) and other groups such as the General Accounting Office (GAO), and the Institute of Medicine (IOM) have reviewed the agency's policies, practices, and regulations. Reports issued following the respective reviews made a number of recommendations as to how FDA might improve the biologics regulations, particularly as they apply to the continued safety of blood products. The relevant reports are: (1) ''Protecting the Nation's Blood Supply From Infectious Agents: The Need for New Standards to Meet New Threats'' by the Subcommittee (August 2, 1996); (2) ''Blood Supply: FDA Oversight and Remaining Issues of Safety'' by GAO (February 25, 1997); (3) ''Blood Supply: Transfusion-Associated Risks'' by GAO (February 25, 1997); and (4) ''HIV and the Blood Supply: An Analysis of Crisis Decisionmaking'' by IOM (July 13, 1995). These reports are on file with the Dockets Management Branch (address above) under the docket number given in the heading of this document.

FDA has reviewed these reports and agrees with the majority of the recommendations contained within them. However, rather than to only respond specifically to the recommendations from the Subcommittee, GAO, IOM, and the public, FDA has convened a number of internal task forces to review a variety of issues related to the regulation of blood and blood products, including how to most appropriately update the existing regulations applicable to blood and blood products. In the future, FDA intends to issue a number of blood-related rulemakings that various FDA task groups are currently preparing. FDA is not describing the specific recommendations it has received and the numerous objectives of the Blood Initiative in this document. Future rulemaking and other notices will describe and discuss specific recommendations and regulatory objectives.

B. Requirements and Recommendations for Testing Donors of Blood and Blood Components

Requirements for testing blood donors for hepatitis B surface antigen and antibody to HIV are currently codified in part 610. The agency has issued various guidance documents to registered blood and plasma establishments providing recommendations for testing for antibody to hepatitis B core antigen, antibody to human T-lymphotropic virus types I and II, antibody to hepatitis

C virus, and HIV–1 p24 antigen. The purposes of the guidance documents are to assist blood establishments in protecting the safety of the blood supply and to establish policies with the intent of promoting consistency in the industry. These guidance documents represent the agency's current thinking on the appropriate testing of human blood donors for evidence of infection due to various communicable disease agents. Through inspection, FDA has determined that blood establishments generally have been following these recommendations. However, there have been instances where there have been variations in testing and in the determination of suitability of the blood based on the testing results. Accordingly, FDA is proposing to require testing consistent with its current recommendations and industry practice. This will help ensure consistency in the blood industry's testing practices, and provide FDA with clear enforcement authority if compliance problems should occur.

The guidance documents referenced in this document or otherwise applicable to the testing of blood donors may be obtained from the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance documents may also be obtained by mail by calling the CBER Voice Information system at 1–800–835–4709 or 301–827–1800, or by FAX by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. Persons with access to the Internet may obtain the documents by using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/publications.htm''.

As part of the Blood Initiative, the agency is proposing to revise part 610 subpart E. Currently, subpart E requires testing for HBV and HIV and the development and administration of a product quarantine and recipient notification (''Lookback'') program when donors test repeatedly reactive for antibody to HIV, or otherwise are determined to be unsuitable when tested in accordance with § 610.45. In response to the recommendations made in various reports addressing the safety of the nation's blood supply mentioned previously, FDA is proposing to: (1) Require screening tests for evidence of infection due to communicable disease agents for autologous donations (blood donations intended to be later reinfused into the donor) in order to reduce the risk of transmission of communicable disease by untested units inadvertently entering the blood supply; (2) require supplemental (additional, more specific) testing of all donations that are repeatedly reactive by screening tests for which there are supplemental (additional, more specific) tests; and (3) codify as requirements those recommendations that FDA has issued that are necessary to ensure blood safety, including testing for evidence of infection due to HIV, HBV, HCV, and HTLV. FDA is considering proposing a general testing regulation for blood and blood components in the future that would require blood establishments to test for additional relevant communicable diseases. Such a rule could impose testing obligations as additional relevant communicable disease agents are identified and FDA approves tests for such agents.

II. Legal Authority

FDA is proposing to issue this new rule under the authority of sections 351 and 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 262 and 264 *et seq.*), and the provisions of the Federal Food, Drug, and Cosmetic Act (the act) that apply to drugs (21 U.S.C. 201 *et seq.*). Under section 361 of the PHS Act, FDA may make and enforce regulations necessary to prevent the introduction, transmission, and spread of communicable disease between the States or from foreign countries into the States (see Sec. I, 1966 Reorg. Plan No. 3 at 42 U.S.C. 202 for delegation of section 361 authority from the Surgeon General to the Secretary of the Department of Health and Human Services (Secretary); see 21 CFR 5.10(a)(4) for delegation from the Secretary to the Food and Drug Administration). Intrastate transactions may also be regulated under section 361 of the PHS Act (see *Louisiana* v. *Mathew*, 427 F. Supp. 174, 176 (E.D.La. 1977)). Testing each donation for evidence of infection due to communicable disease agents would help prevent unsafe units of blood or blood components from entering the blood supply. The focus of the proposed rule is preventing the introduction and spread of communicable disease through transfusion.

All blood and blood components introduced or delivered for introduction into interstate commerce also are subject to section 351 of the PHS Act (42 U.S.C. 262). Section 351(a) of the PHS Act requires that manufacturers must have a license which has been issued upon showing that the manufacturing establishment meets all applicable standards, prescribed in the biologics regulations, designed to insure the continued safety, purity, and potency of the blood and blood components, and that the product is safe, pure, and potent. FDA's license revocation regulations provide for the initiation of revocation proceedings, if, among other reasons, the establishment or the product fails to conform to the standards in the license application or in the regulations designed to ensure the continued safety, purity, or potency of the product (§ 601.5). Section 351 of the PHS Act provides for criminal penalties for violation of the laws governing biologics. Violations can be punishable by fines or imprisonment, or both.

The act also applies to biological products (42 U.S.C. 262(d), as amended). Blood and blood components are considered drugs, as that term is defined in section 201(g)(1) of the act (21 U.S.C. 321(g)(1)) (see *United States* v. *Calise*, 217 F. Supp. 705 (S.D.N.Y. 1962)). Because blood and blood components are drugs under the act, blood establishments must comply with the substantive provisions and related regulatory scheme. Under section 501 of the act (21 U.S.C. 351), drugs are deemed ''adulterated'' if the methods used in their manufacturing, processing, packing, or holding do not conform with current good manufacturing practices (21 U.S.C. 351(a)(2)(B)). Under the proposed rule, blood establishments would be required to test each donation of blood and blood components for evidence of infection due to communicable disease agents. Blood and blood components manufactured from donations that are not tested in accordance with this proposed rule would be considered adulterated under 21 U.S.C. 351(a)(2)(B), and blood establishments, and blood and blood components would be subject to the act's enforcement provisions for violations of the act.

III. Description of the Proposed Rule

This rule is proposed in order to reduce the risk of infection due to communicable disease agents to blood product recipients and to individuals handling blood or blood products including components of a medical device. FDA proposes to require that each donation of human blood or blood component, including those intended for autologous use or as a component of a medical device, be tested for evidence of infection due to HIV, types 1 and 2; HBV; HCV; and HTLV, types I and II. Each donation that tests repeatedly reactive when screened for evidence of infection due to any of the

communicable disease agents would be required to be further tested whenever a supplemental (additional, more specific) test has been approved for such use by FDA. Testing would be required to be performed by a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and registered with FDA in accordance with part 607. When donors test repeatedly reactive, the agency would require deferral of such donors from future donations. Criteria are proposed for release or shipment of human blood or blood components prior to completion of testing, and restrictions on shipment or use of human blood or blood components that test repeatedly reactive when screened for evidence of infection. The proposed rule would also require manufacturers of approved test kits to test human blood donors for evidence of infection due to communicable disease agents to verify an acceptable sensitivity and specificity of each lot of test kit using a reference panel obtained from CBER, when available.

A. Required Testing for Communicable Disease Agents

Proposed § 610.40(a) would require testing for evidence of infection due to the communicable disease agents HIV, types 1 and 2; HBV; HCV; and HTLV, types I and II using screening tests approved for such use by FDA in accordance with the manufacturers' instructions. The agency is not proposing to specify the marker(s) to be tested for, such as a specific antigen or antibody. The purpose of testing is to adequately and appropriately reduce the risk of transmission of communicable disease agents. Thus, one or more tests that would fulfill proposed § 610.40 should be chosen for this purpose.

Historically, tests for new or different markers of infection due to a communicable disease agent have changed as they become more appropriate or the technology in testing has become more sensitive or specific. Therefore, FDA is structuring the proposed regulations so that manufacturers may adopt adequate and appropriate methodologies to protect the safety of the nation's blood supply, without necessitating rulemaking by the agency with the development or advancement of each test method, e.g., FDA recognizes the possibility that nucleic-acid-based screening could replace some current methods of testing. FDA believes that such nucleic-acid-based screening, including ''in-house'' or ''home brew'' screening of blood or blood components for communicable disease agents required under this regulation should be regulated under section 351 of the PHS Act when the blood or blood components are intended for use in preparing a product, including donations for autologous use or as a component of a medical device. Several manufacturers have begun to conduct nucleic-acid-based screening of plasma pools for HIV and HCV under investigational new drugs (IND). FDA considers such nucleic acid testing of plasma pools used to manufacture blood products to be donor screening. FDA intends to issue draft guidance and request public comment on nucleic acid testing in the near future.

As technology advances, FDA intends to regularly issue guidance describing those tests that it believes are adequate and appropriate in reducing the risk of transmission of communicable disease agents. The agency would issue such guidance in draft, giving the opportunity for public comment and for manufacturers to prepare to use any appropriate new testing technologies. In some circumstances, when it is necessary to protect the public health, the agency may, as described under its current Good Guidance Practices (62 FR 8961, February 27, 1997), recommend immediate implementation of the guidance. Consistent with FDA guidance, as discussed in section I.B of this document, it is current practice by the blood industry to test blood donations intended for transfusion or for further manufacture for antibody to HIV, types 1 and 2; HIV–1 p24 antigen; hepatitis B surface antigen (HBsAg); antibody to hepatitis C; and by a serologic test for syphilis. Blood donations intended for transfusion routinely are additionally tested for antibody to HTLV, types I and II, and antibody to hepatitis B core antigen (anti-HBc).

Although blood that is repeatedly reactive for anti-HBc would not be suitable for transfusion even when negative for HBsAg, the plasma from such blood (viz., recovered plasma) would be suitable for manufacture into plasma derivatives. In most cases, blood that is negative for HBsAg but is reactive for anti-HBc would be from a donor who has cleared a hepatitis B infection. Such a donor would still have circulating anti-HBc and presumably would also have circulating anti-HBs, which is hepatitis B neutralizing antibody.

In a small percentage of ''window-period'' cases, the blood could be from a donor who only recently became infected with hepatitis B virus such that the number of viruses in the blood are below detectable limits via antigen testing. While a unit of blood from a donor in window period could be infectious, use of plasma from such a donor, after pooling with plasma from many donors and manufacturing into plasma derivatives, does not present a risk of transmitting hepatitis B to recipients of the plasma derivatives. On the basis of our present knowledge, this safety results from several factors. First, plasma that is negative for HBsAg, even if it is reactive for anti-HBc, would have only a low titer of hepatitis B virus. This titer is further lowered by pooling with many ''true-negative'' units of plasma. Second, virtually all plasma derivatives undergo validated virus removal and/or inactivation procedures in the course of manufacture. Third, there is a high probability that some units of plasma in the pool will be reactive for anti-HBs. This can have the added benefit both of neutralizing any hepatitis B virus present and potentially aiding in its removal during the process of purifying plasma derivatives. For this last reason, present knowledge suggests that excluding plasma that is negative for HBsAg but reactive for anti-HBc could reduce the safety of plasma derivatives because it would reduce the level of anti-HBs in pooled plasma and thereby reduce protection against any contaminating hepatitis B virus present in the pooled plasma.

For the same reasons, FDA does not currently believe that Source Plasma (which is not obtained from Whole Blood donations and is used only for further manufacture) that is negative for HBsAg needs to be tested for anti-HBc.

In January 1995, as part of a National Institutes of Health Consensus Development Conference, a panel of non-federal, nonadvocate experts met to provide physicians and other transfusion medicine professionals with a consensus on infectious disease testing for blood transfusions. One of the issues reviewed was the value of testing for syphilis in protecting the safety of the blood supply. The serologic test for syphilis was introduced in 1938 to prevent the transmission of syphilis through blood transfusions. In the early AIDS era it was thought to have additional value as a marker of high risk behavior, although this benefit has been challenged. The serologic test for syphilis has a high rate of false positives, leading to further supplemental (additional, more specific) testing using specific treponemal confirmatory tests. After discussion, the panel agreed ''Because the contribution of serologic tests for syphilis in preventing transfusion-transmitted syphilis is not understood, the panel concludes that testing of donors for syphilis should continue.'' FDA regulations continue to require the

serologic test for syphilis (see §§ 640.5(a) and 640.65(b)). However, the agency recognizes that many scientists, including some members of the blood banking community, continue to advocate the elimination of the serologic test for syphilis as a testing requirement. The agency is soliciting comments, with supporting data, from the public in regard to the value of donor testing for syphilis as a marker of high risk behavior, as a surrogate test for other infectious diseases, and in preventing the transmission of syphilis through blood transfusion. If the agency receives comments with adequate data supporting the removal of the requirement for a serologic test for syphilis, FDA may proceed with rulemaking to remove the requirements for a serologic test for syphilis, including treponemal and nontreponemal based tests, from part 640.

B. Affected Products

Each donation of human blood or blood components, i.e., whole blood, red blood cells, plasma, sera, platelets, and leukocytes, intended for transfusion or for further manufacturing, would be required to be tested for evidence of infection due to communicable disease agents. For the purpose of this proposed rule, any reference to ''blood or blood components'' will include Source Leukocytes and Source Plasma unless specifically addressed. This proposal includes testing requirements for donations intended for autologous use or as a source material or component of a medical device. Inclusion of testing requirements for donations intended solely for use in a medical device is a safeguard for persons who may be exposed to infectious blood products used in such devices.

Despite the reduced risk of infection when using autologous blood, FDA is concerned that the increased demand to use autologous donations may compromise transfusion safety for both autologous and allogeneic recipients. Recent data from an industry conducted survey show that errors and accidents involving autologous blood occur with sufficient frequency to compromise the safety of both autologous and allogeneic transfusions. Examples of these errors and accidents include the erroneous transfusion of an autologous unit to an unintended recipient; the inappropriate salvage of plasma for further manufacture from untested or infectious disease marker positive autologous units; the breakage of autologous units during laboratory processing or product transport; and clerical errors in inventory management, including inadvertent crossover of autologous units to the allogeneic inventory. Proposed § 610.40 would require uniform testing for both autologous and allogeneic donations, thus significantly reducing any risk to the public health posed by the inadvertent improper use of potentially infectious products.

Unlicensed blood and blood components are often used as components or source material in the manufacture of certain medical devices, including in vitro diagnostic test kits. To apply the current good manufacturing practice (CGMP) for blood and blood components to such products used in the manufacture of unlicensed blood products that are device components or device raw materials, FDA issued a final rule on June 9, 1989 (54 FR 24706), requiring manufacturers of such products to follow the blood CGMP's in 21 CFR part 606. The preamble to that final rule stated that blood products that are device components or device raw materials excluded from the scope of the device CGMP's under § 820.1 (the quality system regulation) are subject to the blood CGMP's in part 606. Violations of part 606 involving such device components or raw materials are subject to enforcement action under section 501(h) of the act.

Accordingly, FDA is proposing in this rule to clarify the applicability of testing for evidence of infection due to communicable disease agents to human blood or blood components used in the manufacture of a medical device.

C. Exceptions

Proposed § 610.40(b)(1) and (b)(2) would exempt Source Plasma, and donations of human blood and blood components intended solely as a component of an in vitro medical device unless they contain viable leukocytes, from being tested for evidence of infection with HTLV, types I and II. Donations of Source Plasma, i.e., the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use, would not be required to be tested for evidence of infection with HTLV, types I and II because HTLV is highly cell-associated in humans and HTLV transmission has not been demonstrated by the transfusion of plasma or by the use of products made from Source Plasma. Currently, in FDA's existing guidance, testing for antibodies to HTLV, types I and II is recommended for donors only if blood components, including plasma, are intended for transfusion.

Under proposed § 610.40(b)(3), FDA would not apply the requirements under § 610.40(a) to certain cases when the human blood or blood components are not intended for commercial distribution or for use in preparing a product. This proposal would be consistent with the current requirements in § 610.45 *Human Immunodeficiency Virus (HIV) requirements*. Such cases include the in-house use (i.e., use within the same establishment) or distribution of samples of blood, blood components, plasma, or sera for: (1) Clinical laboratory testing ; and (2) research purposes, provided that it is not intended for administration to humans or use in manufacturing a product. FDA believes that the proposed exceptions would help ensure the continued public health while not impeding continuing research efforts and the ability to ship blood samples for purposes of clinical laboratory testing.

FDA is requesting comment on whether to exempt from testing for evidence of infection due to communicable disease agents listed in proposed § 610.40(a) each donation of dedicated apheresis donors. Specifically, FDA seeks comments on whether the proposed rule, when finalized, should be revised to permit testing proposed in § 610.40(a) to be completed only once at the beginning of a 30-day period of donation by a dedicated apheresis donor for a single recipient. This procedure is currently practiced in specific clinical situations such as a human leukocyte antigen (HLA) matched or family donor donating as a dedicated donor for a patient being treated for diseases such as aplastic anemia, bone marrow, transplant candidate, or leukemia. The agency is requesting comments on the testing of dedicated apheresis platelet donors, at a minimum, at the beginning of a 30-day period during which other donations may continue without further testing. The agency is also requesting comments on alternatives (including the rationale) to testing each donation that may be applied to autologous donations as well as dedicated apheresis donors for a single recipient. For example, could the added safety resulting from mandatory testing of autologous donations be similarly achieved by both improving procedures or requirements for clearly and permanently marking autologous units to distinguish them from allogeneic units and requiring that they be labeled as untested for infectious disease agents, and if so, what additional factors would favor the choice of one approach over the other.

D. Further Testing

Under § 610.40(a), each donor blood sample would be tested by a screening test approved for such use by FDA, according to the directions supplied by the manufacturer of the test kit. As described in the directions, each tested sample would be determined to be reactive or nonreactive. A reactive result on initial testing (initial reactivity) indicates the possible presence of a marker in the sample. According to the manufacturers' instructions, initially reactive samples are to be tested again, generally in duplicate, and a sample that is found to be reactive on any single retest (i.e., on one or more of the duplicate retests), is considered to be repeatedly reactive. Screening tests are designed to be highly sensitive for the marker specific to the test kit. Because of this sensitivity, the possibility of false positives due to sample contamination, cross reactivity or nonspecific binding exists. In § 610.40(c), the agency proposes to require that repeatedly reactive samples be further tested by a supplemental (additional, more specific) test, when available, that has been approved for such use by FDA. In the past, FDA has issued guidances, discussed previously, that recommend the supplemental testing of repeatedly reactive samples. Although a donor may be deferred from donating based on a repeatedly reactive screening test alone, the supplemental testing would be required so that the following information could be ascertained: (1) Medical information useful in notification and counseling as soon as possible for the donor; and (2) Additional information to be used in evaluating the donor for possible reentry into the donor pool at a future time.

E. Testing Responsibility

Under the regulations, testing of donor blood samples is considered a step in the manufacture of blood products (see § 607.3(d)). Appropriate testing is critical to the continued safety of the nation's blood supply. FDA believes that it is important that FDA know which laboratories are performing such testing and that such laboratories can perform testing adequately. Accordingly, FDA is proposing in § 610.40(d) to require that testing for evidence of infection due to the communicable disease agents designated in § 610.40(a) be performed by a laboratory registered with FDA in accordance with part 607, and certified to perform testing on human specimens under the CLIA (see 42 CFR part 493). In addition, FDA is proposing to remove § 607.65(g), which exempts from registration clinical laboratories that are approved for Medicare reimbursement and which are engaged in the testing of blood products in support of other registered establishments. As a result, such laboratories would need to register with FDA.

F. Release or Shipment Prior to Testing

Under § 610.40(e), FDA proposes to permit, in specified situations, the release or shipment of human blood or blood components before the completion of testing required under § 610.40(a). Section 640.2(f) would be removed. The agency recognizes that there are rare medical emergencies, e. g., where a patient's need for blood is so acute that transfusion is necessary before knowing the results of any communicable disease testing of the blood. FDA believes that the use of untested or incompletely tested blood in such medical emergencies should not be prohibited. Because products other than Whole Blood may need to be released in medical emergency situations, FDA is proposing to place the provision for medical emergency situations in § 610.40(e), which is applicable to all blood products, and to remove § 640.2(f), which is applicable to Whole Blood only.

FDA is proposing in § 610.40(e) to permit, with FDA approval, routine shipment of certain blood components for further manufacturing before testing is completed and the tests results are received by the collection facility. To obtain approval from FDA, the agency would expect the collection facility and the manufacturing facility to whom the blood product is being shipped, to submit with their request specific procedures for collection, shipment, and quarantine of a product before testing is completed. Once the procedures have been approved, manufacturers may then begin to ship products prior to the completion of testing. This proposal is intended to ensure the continued availability of biological products, such as interferon, that are important to the medical community and which require rapid preparation from blood.

The provisions for emergency release and shipment prior to completion of testing would require appropriate documentation, that testing would be performed as soon as possible, and that the results would be provided promptly to the consignee.

G. Restrictions on Shipment or Use

In § 610.40(f)(1), FDA is proposing to require that blood and blood components testing repeatedly reactive when screened for evidence of infection due to a communicable disease agent designated in proposed § 610.40(a), or collected from a donor with a record of a repeatedly reactive test result, shall not be shipped or used to prepare any product, including products not subject to licensure, except as described in section III of this document. FDA believes that inappropriate handling, labeling, or use of such blood could be hazardous to the public health. Therefore, FDA is proposing to restrict the shipment or use of such blood and blood components.

Under proposed § 610.40(f)(2)(i), the restriction on shipment or use of blood or a blood component that tests repeatedly reactive when screened for evidence of infection due to a communicable disease agent listed in proposed § 610.40(a) would not apply to units intended for autologous use. Autologous blood or blood components would be required to be appropriately labeled in accordance with § 606.121(i) and with the Biohazard legend demonstrated in the codified section. Under proposed § 610.40(f)(2)(ii), blood establishments intending to ship or use human blood or blood components for further manufacture that test repeatedly reactive when screened for evidence of infection due to a communicable disease agent listed in proposed § 610.40(a) would apply for approval by FDA. Application for approval would be submitted as part of the license application or a supplement to the approved license. For unlicensed products, application for approval would be submitted in accordance with § 640.120 as discussed in section K of this document. The written application would describe the intended use of the blood or blood component, and the procedures for collecting, handling, labeling, and shipping the blood. Blood and blood components are required to be labeled in accordance with §§ 606.121 and 640.70, as appropriate. Repeatedly reactive blood or blood components would be required to be labeled as repeatedly reactive for the applicable marker for the identified communicable disease agent and display the Biohazard legend. If repeatedly reactive blood or blood components are to be used for further manufacturing into injectable products, the blood or blood component would be required to be labeled with the exempted use specifically approved by FDA. For manufacturing into noninjectable products, such as in vitro diagnostic products when there is no alternative source such as monoclonal antibody, repeatedly reactive blood or blood components would be required to be labeled with the statement ''Caution:

For Further Manufacturing Into Non-Injectable Products For Which There Are No Alternative Sources''. Distribution may not commence until approval is granted.

Under proposed § 610.40(f)(3), FDA would permit the use of blood or blood components from a donor who was deferred as a result of testing repeatedly reactive on a screening test(s) for specified communicable disease agent(s) if the blood or blood components test negative for those same disease agent(s) and the donor has been shown to be suitable to donate blood by a method or process described in a supplement to the establishment's license and approved for that purpose by FDA. (Such methods are called ''donor reentry'' algorithms.) FDA has identified such methods or processes in the agency's guidance documents, discussed previously, in the format of algorithms, or step-by-step procedures designed to reenter the donor into the donor pool, when appropriate.

There are occasions when human blood or blood components that test repeatedly reactive when screened for evidence of infection due to a communicable disease agent listed in proposed § 610.40(a) are needed for further manufacture, e.g., when used in the manufacture of certain in vitro diagnostic products. The agency proposes in § 610.42 to require that a repeatedly reactive unit used for further manufacturing into an in vitro diagnostic product be labeled as repeatedly reactive for the applicable marker of infection due to the identified communicable disease agent. For an in vitro diagnostic product manufactured from a repeatedly reactive unit, the agency would require in § 610.42 that the manufacturer label the product in accordance with 21 CFR 809.10 and that a warning be included stating that the product was manufactured from a donation that tested repeatedly reactive for the appropriate marker of infection for the identified communicable disease agent. This would be required to help prevent the spread of communicable disease in those handling the product, (i.e., such labeling should result in handlers taking appropriate precautions for their and other's safety).

H. Compliance with §§ 610.46 and 610.47 (''Lookback'' requirements for HIV)

Current § 610.45(d) requires the blood establishment to comply with §§ 610.46 and 610.47 and perform testing, quarantine, consignee notification and recipient notification when a blood donor tests repeatedly reactive for HIV or when the blood establishment has been made aware of other test results indicating HIV infection. The agency is not proposing to include this requirement in this proposed rule. However, in future rulemaking, the agency will propose new regulations for ''Lookback'' when donors test repeatedly reactive for HCV, comparable to those requirements currently applicable for donors testing repeatedly reactive for HIV. The new ''Lookback'' proposed regulations will consolidate in one section the current requirements for HIV ''Lookback'' and the proposed HCV ''Lookback'' requirements. In the event that finalization of the new proposed ''Lookback'' rule is delayed, the agency intends to issue the current language in § 610.45(d) as § 610.40(g) with specific paragraph and section cites revised.

I. Donor Deferral

Once the donor (except for autologous donors or other donors as discussed in section III.I of this document), at the time of donation, tests repeatedly reactive by a screening test(s) performed in accordance with proposed § 610.40(a), the blood or blood components from that donation are to be quarantined and either destroyed or excluded from use in transfusion; and, based on the particular marker that tests repeatedly reactive, the donor will then be either deferred from donating in the future or deferred if a similar result is obtained on any subsequent donation. Similar provisions under §§ 640.5 and 640.65 apply to donations reactive for syphilis, however, some additional exceptions apply. Blood establishments are currently required under § 606.160 to maintain records of results and interpretation of all tests and retests, and a record from which unsuitable donors may be identified so that products from such individuals will not be distributed. Proposed § 610.41 explicitly would require the deferral of donors based on testing. FDA is issuing elsewhere in this issue of the **Federal Register**, notice and comment rulemaking proposing to require the notification of donors of their deferral from donating in the future and the reason for the deferral (such as health history or test results). FDA also intends to issue notice and comment rulemaking in the near future proposing donor suitability criteria.

In proposed § 610.41(a), donors who test repeatedly reactive for HTLV, types I and II, or anti-HBc only once, would be permitted to donate again without being deferred from further donation unless there is further testing using an approved supplemental (additional, more specific) test. This proposal is consistent with FDA's guidance to all registered blood establishments dated August 19, 1997, entitled ''Donor Screening for Antibodies to HTLV–II.'' Once supplemental tests for HTLV, types I and II are approved, donors would be deferred after only a single repeatedly reactive donation similar to most other screening tests. It is FDA's expectation that donor reentry algorithms would become feasible at that time. However, until such time, upon testing repeatedly reactive a second time for HTLV, types I and II or anti-HBc, the donor would be deferred.

FDA is proposing in § 610.41(b) to permit donors testing repeatedly reactive for HTLV, types I and II or anti-HBc to serve as donors of Source Plasma (See section III.C of this document for discussion on the risk of transmitting HTLV, types I and II through Source Plasma; see section III.A of this document for discussion on the use of plasma from donors who test repeatedly reactive for anti-HBc). However, the agency is requesting comments on this proposal that permits such donors to donate Source Plasma to be used in the manufacture of plasma derivatives as it relates to exposure to other possible risks, such as the association of HTLV infection with abuse of intravenous drugs.

Proposed § 610.41(c)(1) permits deferred donors to donate blood and blood components when used in accordance with § 610.40(f). In proposed § 610.40(f), the agency proposes that blood and blood components that test repeatedly reactive when screened for evidence of infection due to communicable disease agents listed in proposed § 610.40(a) would not be shipped or used except for autologous use or for purposes or under conditions approved in writing by FDA. Such approval may also be obtained under current § 640.120.

The agency is proposing in § 610.41(c)(2) to restrict the use of blood or blood components from donors showing evidence of infection due to hepatitis B virus when tested in accordance with § 610.40(a) and (c). Such blood and blood components may be approved for use only as a source of antibody to hepatitis B surface antigen (anti-HBS, Hepatitis B neutralizing antibody) for the preparation of Hepatitis B Immune Globulin (Human) or as a component of a medical device. Use of such blood or blood components would be prohibited in the manufacture of other biological products. The agency requests comments on the use of vaccinated donors for HBV as an alternative to using donors previously showing evidence of infection due to

hepatitis B virus in the preparation of Hepatitis B Immune Globulin (Human).

In proposed § 610.41(d), the agency would not defer donors of blood and blood components from further donations, if the donor was found negative by an approved specific treponemal test (confirmatory test for syphilis) despite a reactive screening test. Accordingly, if the donor tests positive by the more specific test, then the donor would be deferred and reentered into the donor pool only in accordance with proposed § 610.41(e). Donors of Source Plasma testing reactive for the serologic test for syphilis, shall follow the procedure provided in § 640.65(b)(2)(ii), (b)(2)(iii), and (b)(2)(iv).

J. Use of Reference Panels by Manufacturers of Test Kits

For a number of years, FDA has made available reference panels (also known as lot release panels) of known reactivity to a marker of infection due to a communicable disease agent. These reference panels are used by manufacturers in the qualitative and semi-quantitative evaluations of their in vitro tests to detect a defined marker of infection due to the identified communicable disease agent. FDA is proposing to move the requirements for reference panels for hepatitis B test kits to proposed § 610.44 and add that reference panels be used when available for all the test kits for communicable disease agents identified in proposed § 610.40(a) and for all approved HIV tests. The agency would require the use of these regulatory reference panels obtained from the Center for Biologics Evaluation and Research (CBER) or from an FDA designated source, when available, to provide a verification by the manufacturer of the sensitivity and specificity of each lot of test kit approved for use in testing donations of human blood and blood components. This release criterion would be applied to lots of test kits produced by licensed manufacturers or lots produced by manufacturers pursuing licensure of such tests. Once a reference panel is assembled and available for use in lot release testing, the Director, CBER, would send a letter informing all licensed manufacturers of the appropriate test kit of the availability of the reference panel and of the date the agency believes the new reference panel should be put into use for lot release testing. This will usually be followed by a notice in the **Federal Register**. Lots of test kits found to be not acceptable for sensitivity and specificity would be prohibited from release. By inserting the requirement in this section, FDA is attempting to emphasize the need for reference panels to manufacturers of blood and blood components so that they may use the appropriately released lot of test kits. Accordingly, the agency is proposing to remove § 660.42, a requirement for a reference panel for hepatitis B surface antigen, and include the use of reference panels by manufacturers of test kits in proposed § 610.44 for better consolidation.

K. Use of § 640.120–Alternative Procedures

FDA recognizes that as technology and scientific knowledge advance, there will continue to be instances when a regulation will become outdated or where unanticipated circumstances may warrant a departure from an approach detailed in the regulations. In order to be more responsive to improved technologies, increased scientific knowledge, and concerns about the continued availability of blood and blood products, the agency has issued a regulation at § 640.120, which allows the Director, CBER, to approve an exception or alternative to any requirement in subchapter F of chapter I of title 21 of the Code of Federal Regulations regarding blood, blood components, or blood products. The Director, CBER, would approve such an exception or alternative only if, in the judgment of the Director, CBER, the safety, purity, potency, and effectiveness of the final product is adequately ensured. The Director, CBER, may request additional data or information from the person who has requested permission for an exception or alternative before granting the request. Any exception or alternative to the proposed rule, once finalized, would proceed under § 640.120.

L. Removal of § 610.45

With the reconstruction and streamlining of the regulations in regard to testing requirements for communicable disease agents, the agency is proposing to remove § 610.45, human immunodeficiency virus (HIV) requirements, because it has been incorporated into the revision of proposed§ 610.40.

IV. Analysis of Impacts and Initial Regulatory Flexibility Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Public Law 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). The Regulatory Flexibility Act requires agencies to analyze whether a rule may have a significant impact on a substantial number of small entities and, if it does, to analyze regulatory options that would minimize the impact. Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

OMB has determined that the proposed rule is a significant regulatory action as defined by the Executive Order and so is subject to review. Because the rule does not impose any mandates on State, local, or tribal governments, or the private sector, that will result in any one year of $100 million or more, FDA is not required to perform a cost-benefit analysis according to the Unfunded Mandate Reform Act.

The Regulatory Flexibility Act requires agencies to prepare a Regulatory Flexibility Analysis for each rule unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Although the proposed rule is not expected to have a significant economic impact on a substantial number of small business entities, a precise impact is uncertain. Therefore, the agency has prepared an Initial Regulatory Flexibility Analysis.

A. Objectives and Basis of the Proposed Action

FDA is taking this action as part of the agency's ''Blood Initiative'' in which FDA is reviewing and revising, when appropriate, its regulations, policies, guidance, and procedures related to blood and blood products, including plasma derivatives. The basis for this proposed rule is to help protect the safety and ensure the quality of the nation's blood supply, and to promote consistency in the industry. Under the biologics licensing and quarantine provisions of the PHS Act (42 U.S.C. 262–264) and the drug, device, and the general administrative provisions of the act (21 U.S.C. 351–353, 355–360, and 371–374), FDA has the authority to issue regulations designed to protect the public from unsafe or ineffective biological products and to issue regulations necessary to prevent the

transmission of communicable diseases into the United States or from one State to another. Under these statutory authorities, the agency is proposing to: (1) Require screening tests for evidence of infection due to communicable disease agents for autologous donations in order to reduce the risk of transmission of communicable disease by untested units entering the blood supply inadvertently; (2) require supplemental (additional, more specific) testing of all donations that are repeatedly reactive by screening tests for which there are supplemental tests; and (3) codify as requirements those recommendations that FDA has issued that are necessary to ensure blood safety, including testing for evidence of infection due to HIV, HBV, HCV, and HTLV.

B. Nature of the Impact

The proposed rule requires that each donation of human blood or blood component, including those intended for autologous use or as a component of a medical device, be tested for evidence of infection due to HIV, types 1 and 2; HBV; HCV; and HTLV, types I and II. Each donation that tests repeatedly reactive when tested for evidence of infection due to any of the disease agents would be required to be further tested whenever a supplemental, more specific test has been approved for such use by FDA. FDA is proposing to require that the testing be done by a laboratory that is registered with FDA and CLIA-certified. The proposed rule also contains provisions for appropriate deferral of donors based on test results, and exemptions for Source Plasma from being tested for evidence of infection from HTLV, types I and II. FDA is proposing to permit shipping of units prior to testing if appropriate procedures are developed for collection, shipment and quarantine to protect against unnecessary communicable disease risks from use of shipped units later found to test repeatedly reactive. Under the proposed rule, allogeneic donations that test repeatedly reactive shall not be shipped except in situations specifically approved by FDA; however, repeatedly reactive autologous units may be shipped with labeling to indicate biohazard.

The rule would also require manufacturers of test kits, approved for use in testing donations of human blood and blood components for these disease agents, to verify an acceptable sensitivity and specificity of each lot of test kit, using a reference panel obtained from CBER or an FDA designated source, when available.

1. The Type and Number of Entities Affected

The proposed testing of donations from allogeneic and autologous donors of blood and blood components will affect all blood and plasma establishments that collect blood and blood components from such donors. FDA's Office of Blood Research and Review (OBRR) has record of 2,801 registered blood and plasma establishments, including 487 plasma centers and 2,314 blood centers. Most Source Plasma centers are commercial establishments with paid plasma donors. By contrast, whole blood donors in the United States are volunteers. The most recently published survey of the blood industry was conducted in 1992 (Ref. 1), and the aggregate figures for blood collection reported in the 1992 survey are generally consistent with the aggregate numbers (i.e., 14 million blood donations) currently provided by the American Association of Blood Banks (AABB) (Ref. 2), although the number of registered facilities is now somewhat higher. The 1992 survey of U.S. blood establishments reported on 2,093 entities, including 157 distinct regional and community blood centers. Data on activities of the regional and community blood centers were obtained as responses to the AABB's 1993 Institutional Membership Questionnaire, directly from the American Red Cross, or in the case of non-AABB centers, from responses to questionnaires mailed from the Center for Blood Research. According to the 1992 survey, 1,936 hospitals listed as members of the AABB, are involved in blood collection. These hospitals are a subset of the American Hospital Association (AHA) list of 5,288 hospitals presumed to transfuse blood.

According to the 1992 survey, all U.S. blood establishments were estimated to collect a total of 13,794,000 units of blood. Allogeneic donations accounted for 87.2 percent (12,035,000 units), directed donations accounted for 3.2 percent (436,000 units) and autologous donations comprised 8.1 percent (1,117,000 units) of the total. Regional and community blood centers report receiving 702,000 of the total autologous units, and hospital blood centers collected an estimated 415,000 units. Based on information published by the AABB and the American Red Cross regarding allogeneic donations, and communications with experts in the blood banking industry regarding the testing of autologous donations, FDA believes that all blood donations currently collected by the regional and community blood centers, and all of the allogeneic donations collected by hospitals are already being tested for the specified disease agents. FDA also estimates that approximately one-third to one-half of the autologous donations currently collected by hospitals are already being tested for HIV, types 1 and 2, HBV, HCV, and HTLV, types I and II. In the following analysis, an approximate midpoint of 40 percent is used as the assumed percentage of hospital-collected autologous donations already being tested for the specified disease agents.

In 1997, the Government Accounting Office (GAO) estimated that approximately 12 million donations of Source Plasma were collected by plasma centers (Ref. 3). Although the precise number of those donations currently tested for HIV, types 1 and 2, HBV, and HCV is not reported, FDA assumes that virtually all donations are currently being initially screened for the communicable disease agents specified for plasma donations in the proposed rule. However, based on GAO reported variations in the plasma industry's confirmatory testing of repeat reactive donations, it is also assumed that supplemental confirmatory testing for HCV is not widely practiced at present.

The proposed requirements for manufacturer testing of approved test kits will entail manufacturers' use of CBER regulatory reference panels to provide verification of the specificity and sensitivity of each lot of test kit approved for use in testing donations of human blood. This release criterion would be applied to lots of test kits produced by licensed manufacturers or lots produced by manufacturers pursuing licensure of such tests. FDA estimates that the number of manufacturers of kits for the four disease agents specified in the rule currently ranges from six to seven establishments per disease agent. It is also possible that some additional number of manufacturers may pursue licensure of such kits in future years, although the total number is likely to remain small because of the expected limits of demand for such tests.

FDA currently has reference panels available for all of the disease agents specified in the proposed rule, and has made the panels available to all currently licensed manufacturers of test kits. To the agency's knowledge, all currently licensed manufacturers covered by the proposed rule are already performing the proposed tests to comply with their own quality assurance standards. The proposed rule is therefore expected to introduce no substantial impact on these establishments.

2. Estimated Impact of Proposed Requirements for Donor Testing

The proposed rule provisions for donation testing, appropriate handling, labeling, and distribution will involve a one-time effort by all blood establishments to review and modify current blood donor testing, handling, and recordkeeping protocols to comply with the proposed rule. The rule will also involve a yearly increase in donor testing for establishments that currently do not test both allogeneic and autologous blood and blood component donations.

The one-time effort to review and modify current standard operating procedures (SOP's) is expected to vary among establishments, depending on whether the establishment already engages in testing and labeling both autologous and allogeneic blood donations for the specified set of disease agents. For establishments that already perform testing and labeling of both autologous and allogeneic donations (i.e., all plasma centers collecting only for allogeneic use, regional and community blood centers, and 40 percent of hospital collection sites), FDA estimates that it would take approximately 8 hours of staff time to reconcile the proposed regulations against the facility's current standards. This process could be performed by a technical specialist who acts as a regulatory reviewer or manager of quality assurance. Based on the total average hourly compensation of $25.67 for professional specialty and technical occupations in the health services industry, as reported by Bureau of Labor Statistics for March 1997, the cost would be approximately $205, for each of the blood centers and an estimated 40 percent of the hospital blood centers. For establishments that already perform the proposed testing on allogeneic, but do not test autologous donations, FDA assumes that approximately 16 hours of staff time would be required to reconcile and expand the current facility standards to comply with the requirements of the proposed regulation. The cost in this case would be $411 per facility. It is also assumed that all facilities perform careful labeling and recordkeeping on autologous units donations, and that recordkeeping will include more infectious disease information but will not require substantially more time than is already allocated. Thus, the total one-time cost for the industry is estimated to be $813,554 (2,800 establishments - 1,936 hospital blood centers) x $205 + (1,936 x 0.40 x $205) + (1,936 x 0.60 x $411).

The yearly increase in cost of testing for the 1,162 hospitals assumed not to currently test all donations is based on a proportional extrapolation (60 percent of donors) from the estimated number of autologous donations collected in hospital blood centers, as reported in the 1992 blood collection survey (415 units); the estimated cost per required test; and an estimated rate of 0.19 percent HCV repeat-reactive donations reported by the American Red Cross, based on donations received between January 1996 and June 1997. The cost for HIV, types 1 and 2 is estimated to be approximately $5 per test (Ref. 4); the cost per test for HBV, i.e., HBsAg and anti-HBc, are respectively estimated to be $39.20 (Ref. 5) and $38.59; the cost of HCV–EIA and supplemental assay are respectively estimated to be $49.90 and $114.50 (Ref. 6) per test; and the cost of HTLV, types I and II is estimated to be $5.00 per test (Ref. 7). The total yearly increase in cost for the industry, based on these factors, is estimated to be $34,316,570 (415,000 x .60 x [($5.00 + $39.20 + $38.59 + $49.90 + $5.00) + 0.0019 x $114.50)].

The yearly increase in cost for the plasma industry is based on the assumption that potentially all plasma centers will need to begin routine followup testing on donations that test repeatedly reactive for hepatitis C. Assuming an average 0.18 percent (0.0018) rate of HCV repeatedly reactive donations, an annual volume of 12 million donations and the cost of $114.50 per supplemental HCV test, the annual cost is estimated to be no greater than $2,514,420. FDA recognizes that the cost may actually be less if a substantial fraction of HCV repeatedly reactive donations collected by the plasma centers already undergo confirmatory testing.

In summary, the proposed rule would result in an estimated one-time cost of $813,554, and a total annual cost of $36,830,990 ($34,316,570 + $2,514,420) to the blood and plasma industries.

3. Expected Benefits of the Proposed Rule

The proposed rule is intended to increase the safety of all blood and blood component products by providing recipients with increased protection against communicable disease transmission. The rule addresses exposures that may occur through accidents and errors in administration of autologous as well as allogeneic blood units. For example, AABB Anonymous Survey Report included reports of erroneous transfusions (1.2 percent of respondents), untested recovered plasma salvaged (3.7 percent), units lost in transit (12.3 percent), units broken in the lab (33.6 percent), and units broken outside the lab (32.2 percent), as well as other errors (9.8 percent) (Ref. 17). The reduction in communicable disease risk already achieved among allogeneic blood transfusions as a result of infectious disease testing of donors has been quite dramatic. For example, as a result of expansion of blood donor screening and improved laboratory tests, it is now estimated that the chances of transfusion-related HIV infection have decreased to between 1 in 450,000 to 660,000 per unit of blood (Ref. 8). HCV and HBV transfusion risks have also declined. In 1994, 4.3 percent of all HCV infections were transfusion-related, compared to the current rate of 0.02 percent to 0.05 percent. Similarly, although 5.7 percent of the general population is estimated to be seropositive for HBV, the risk of HBV transfusion transmission is currently estimated to be 1 in 200,000 transfused units.

Although the impetus for autologous donation is often the donor's desire to avoid risk of infection from other donors' blood, studies comparing the prevalence of disease markers in autologous donations compared to allogeneic donations have found the incidence of positive disease markers for first time donations among autologous donors to be similar to that among first-time allogeneic donors. Moreover, the rate among first-time autologous donors was generally higher than that found among repeat allogeneic donors (Ref. 9). The finding of positive markers for an allogeneic donation, however, would result in a blood bank's rejection of the donor unit. By contrast, the disease-positive autologous unit would be retained and potentially stored in the same freezer as the screened allogeneic units. Without the proposed requirement for infectious disease testing and labeling, the label of a disease-positive autologous unit may not indicate that the unit presents a potentially infectious disease risk. The accidental and inadvertent use of such units may expose unwitting recipients to a higher than acceptable risk.

The gravity of the disease risks addressed by the proposed rule are widely recognized. Transfusion of HIV, the virus that causes AIDS, continues to cause great concern. Human T cell leukemia/lymphoma viruses types I and II were identified in the early 1980's. Infection with the virus is associated with tropical spastic paraparesis, adult T-cell leukemia/lymphoma, and some inflammatory disorders (Lapane et al.). Although the virus is primarily sexually

transmitted, it can also be transmitted through blood transfusion.

HBV is a major cause of acute and chronic hepatitis, cirrhosis and primary hepatocellular carcinoma worldwide. The Centers for Disease Control and Prevention (CDC) estimated that in 1985 approximately 300,000 persons became infected with HBV. Prior to the development of hepatitis B screening tests, transfusion-related risks were significant. A retrospective testing of blood donors using first generation tests for the presence of HBsAg found that over half of recipients of HBsAg-positive blood developed hepatitis (Ref. 10). Of the current pool of 1 to 1.25 million HBV carriers, approximately 25 percent will develop chronic hepatitis which will progress to cirrhosis and carriers have a risk of liver cancer that is 12 to 300 times higher than noncarriers. An estimated 4,000 persons die each year from hepatitis B-related cirrhosis, and more than 800 die from primary hepatocellular carcinoma (PHC). The lifetime medical cost per case of PHC and cirrhosis is estimated to be $96,500 (Ref. 11).

Epidemiologic and experimental studies indicate that HCV is primarily transmitted by the parenteral route. Persons at increased risk of acquiring hepatitis C include parenteral drug users; health-care workers with occupational exposure to blood; hemodialysis patients; and recipients of whole blood, blood cellular components or plasma. Transfusion of blood or blood products, which accounted for a substantial proportion of HCV infections acquired more than 10 years ago, is now an uncommon means of transmission. CDC estimates that 150,000 to 170,000 new HCV infections occur annually in the United States (Ref. 12). Of patients with transfusion-associated chronic non-A, non-B hepatitis who undergo biopsy within 5 years after onset, at least 40 percent have histologic evidence of chronic active hepatitis and 10 to 20 percent have evidence of cirrhosis (Ref. 13). An estimated 30 percent of those infected will eventually die of liver-related causes, an estimated 8,000 patients per year. Although some HCV patients have been found to respond to interferon therapy, the average cost of care per year for persons with liver disease from chronic hepatitis C is estimated to range from $24,600 for patients without interferon-alpha therapy to $26,500 per year for those receiving a 12-month course of therapy. The latter has been estimated to provide patients with an additional 0.37 quality-adjusted life years (Ref. 14). As described previously, the requirement of HIV, types 1 and 2; HBV; HCV; and HTLV, types I and II testing for all blood and blood component donations, including those for autologous donations, significantly reduces the U.S. population's exposure to the morbidity and mortality risks associated with these diseases, and their attendant costs.

4. Small Entity Impact

The information available to characterize the relevant volumes of affected blood and plasma products is limited. Although the proposed rule is not expected to have a significant impact on a substantial number of small entities, the impact on blood and plasma establishments that might qualify as small entities is uncertain. The FDA has therefore prepared an Initial Regulatory Flexibility Analysis. The blood and plasma establishments affected by the proposed rule are included under the major Standard Industrial Code (SIC) group 80 for providers of health services. According to section 601 of the Regulatory Flexibility Act of 1980, the term ''small entity'' encompasses the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' According to the Small Business Administration (SBA), a small business within the blood industry is an enterprise with less than $5 million in annual receipts. A small organization is a not-for-profit enterprise which is independently owned and operated and is not dominant in its field. A ''small governmental jurisdiction'' generally means governments of cities, counties, towns, townships, villages, school districts, or special districts with a population of less than fifty thousand.

As described in the foregoing analysis, hospitals that do not currently test autologous donations for HIV types 1 and 2, HBV, HCV, and HTLV types I and II are expected to be the primary entity affected by the proposed rule. However, the extent of the small business impact is uncertain. Although the details of blood collection at hospitals are not available, FDA examined other data to develop a preliminary assessment of small business impact. The size of U.S. hospitals varies substantially. The 1998 American Hospital Association (AHA) survey data (Ref. 15) indicate a total of 5,134 U.S. registered community hospitals grouped into 8 bedsize categories. The average annual revenues for facilities in these bedsize categories range from approximately $5.5 million to $513 million. However, since many hospitals are not-for-profit or are operated by State and local governments, the SBA annual receipts criteria for small businesses would not apply to these facilities. Of the 5,134 U.S. community hospitals included in the AHA report 1,330 are under the control of State and local government, 3,045 are nonprofit institutions, and the remaining 759 are reported to be investor-owned.

The number of hospitals that would meet at least one of the various SBA definitions for small entities is uncertain. According to the AHA statistics for 1998, the smallest reported hospital size category includes 262 hospitals with 6 to 24 beds, and total gross revenues of $1.43 billion, yielding average revenues of $5.46 million. FDA assumes that the 11 facilities reported to be investor-owned within this bedsize category could qualify as small entities. Although it is possible that all nonprofit hospitals may qualify as small entities, it appears that a number of facilities might be excluded from that definition because they are reported to be hospitals in a system. According to the AHA survey definition, ''hospitals in a system'' refer to those ''hospitals belonging to a corporate body that owns and/or manages health provider facilities or health-related subsidiaries; the system may also own non-health-related facilities.'' The AHA currently has record of 1,592 hospitals that are non-federal and nonprofit (including State and local government controlled) that are hospitals in a system. If these facilities were excluded, FDA estimates that 2,783 [1,330 State and local + 3,045 nonprofit - 1,592 in-a-system] non-federal, nonprofit hospitals may qualify as small entities. Thus, a total of 2,794 [2,783 + 11] hospitals might qualify as small entities.

The agency does not know how many of the estimated total of 415,000 autologous units would be collected at hospitals qualifying as a ''small entity,'' nor how many of those establishments are already performing the proposed testing for autologous donors (as noted in the earlier cost analysis, an estimated 40 percent of all hospital-based autologous collections already include blood testing). Some of the hospitals that would be classified as small entities will already be testing autologous donors as required by the proposed rule, and are therefore expected to incur an estimated one-time cost of $205, as described earlier. Other small establishments, that begin autologous donor testing in compliance with the proposed rule, will incur an estimated $411 one-time cost, and yearly costs of new testing based on the number of autologous donors at their facility. The following analysis of potential impact focuses on the annual blood testing costs, which represent the largest

component of cost impact. The analysis assumes that the collections of autologous units may be distributed across hospitals of different size in proportion to the hospitals' share of all reported inpatient surgeries. Table 1 estimates the percentage of all inpatient hospital surgeries, based on the number of inpatient surgeries reported to AHA as performed by hospitals in different bedsize categories. This percentage is used to estimate a share of the total of 415,000 autologous units collected by hospitals in each bedsize category, for which testing would be newly required under the proposed rule. The number of autologous units per hospital within a bedsize category is based on the total estimated autologous units per bedsize category divided by the total number of hospitals reported for that size category. These estimates (rounded to the nearest whole unit) are presented in the rightmost column of the Table 1.

TABLE 1.—ESTIMATED AUTOLOGOUS BLOOD UNITS PER HOSPITAL BASED ON ESTIMATED SHARE OF INPATIENT SURGERIES BY BEDSIZE CATEGORY AND TOTAL HOSPITAL COLLECTIONS OF AUTOLOGOUS UNITS

Bedsize Category	Non-federal Hospitals	Estimated percent inpatient surgeries	Estimated share of 415,000 collected autologous units	Estimated autologous units per hospital
6 to 24	262	0.21	857	3
25 to 49	906	2.02	8,364	9
50 to 99	1,128	6.03	25,029	22
100 to 199	1,338	19.38	80,407	60
200 to 299	692	20.99	87,095	126
300 to 399	361	16.24	67,398	187
400 to 499	196	12.17	50,506	258
500 +	251	22.97	95,343	380

The cost impact of testing autologous blood collections is based on the above estimates of autologous units per hospital, and the earlier estimated average HIV, HCV, HTLV, and HBV testing cost per donation of $137.82 [$5.00 + $49.90+ $5.00 $38.50 + $39.20] + [0.0019 x $114.50]. The estimated annual cost impact per hospital, by bedsize category, is shown in the Table 2. To provide some perspective on relative impact, the newly-incurred cost for autologous unit testing is also shown as a percentage of average annual gross revenues per hospital. The notification cost is estimated to be approximately 0.01 percent of the average annual gross revenues for every size category.

TABLE 2.— ESTIMATED DOLLAR COST PER HOSPITAL FOR AUTOLOGOUS BLOOD TESTING AND ESTIMATED COST AS A PERCENTAGE OF AVERAGE ANNUAL REVENUES

Bedsize Category	Estimated Cost per Hospital at $138 per Newly Tested Unit	Gross Annual Revenue per Hospital (Millions)	Autologous Blood Testing Cost as Percent of Gross Annual Revenue
6 to 24	$451	$5.459	0.01
25 to 49	$1,272	$12.606	0.01
50 to 99	$3,058	$27.711	0.01
100 to 199	$8,282	$74.803	0.01
200 to 299	$17,346	$153.988	0.01
300 to 399	$25,731	$236.917	0.01
400 to 499	$35,514	$329.161	0.01
500 +	$52,351	$513.066	0.01

These findings of this analysis suggest that the relative cost impact may be fairly consistent across hospitals of different sizes, if the number of affected autologous units per bedsize category is proportionate to the number of inpatient surgeries performed by hospitals in different size categories. However, the distribution of affected autologous units across hospitals of different size and types of ownership is currently unknown. Because this information is essential for the estimation of the economic impact on small entities, FDA requests industry comment on the anticipated numbers of affected units of autologous blood and their distribution across hospitals in the industry, particularly those units collected by hospitals that can be classified as small entities.

Regardless of size, the net cost impact for hospitals that must begin testing autologous units may be limited because the cost of the require testing may generally be shifted to patients or to third-party payers, including Medicare. For example, the cost of units or packed red blood cells or blood components, including costs of processing and administration, are covered under both Medicare Part A and Part B (Ref. 16). Currently, Medicare pays for all but the first 3 pints of blood per calendar year. A Medicare beneficiary may choose to pay for or replace the first three units of blood, the annual blood deductible.

The specific requirements and anticipated costs for changes in SOP's for donation collection, testing, labeling, quarantine, and distribution are described previously. All blood establishments are already engaged in a substantial amount of donation testing, recordkeeping, unit labeling, and control. For some hospital blood centers, these activities may be expanded. However, as indicated previously, it is not clear whether the establishments most affected could be characterized as small business entities.

The number of plasma facilities that would qualify as small entities is also uncertain. According to the General Accounting Office (Ref. 16) approximately 370 paid plasma

collection centers annually collect about 11 million liters of plasma, the vast majority of which is processed by four companies: Alpha Therapeutic Corp., Baxter Healthcare Corp., Bayer Corp., and Centeon LLC. FDA estimates that approximately 90 percent of these plasma collection centers are owned by companies that operate a number of centers. Although the agency is uncertain about the level of revenues for these companies, it is considered likely that most would have annual receipts of $5 million or more per year. The remaining 10 percent of paid plasma collection centers may qualify as small business establishments. The potential impact on these facilities will be a function of the number of donors and the HCV repeatedly reactive findings among donors at their facility. If the estimated 12 million plasma donations were evenly distributed over the 487 registered facilities, each facility would average 25,000 donations. Assuming approximately 8 units per plasma donor per year (Ref. 16) each facility would average 3,125 donors, approximately 6 [0.0018 x 3,125] of whom might test repeatedly reactive for HCV and require supplemental testing. The expected cost of the additional testing would then be $687 [$114.50 x 6] per facility per year.

In addition to these for-profit entities, the remaining 100 or so plasma collection facilities, of the total of 487 registered facilities, function within blood collection centers that are operated by the American Red Cross, or are independently operated. The independently operated, not-for-profit blood collection centers would likely qualify as small entities. The added impact of the proposed rule on plasma collection performed at blood collection facilities is expected to be small, however, because the required testing would already be performed for whole blood donation.

FDA has considered several alternatives for lessening burden on small entities. The first alternative would be to not issue additional requirements for testing of allogeneic or autologous donations for evidence of infection due to communicable disease agents and continue with the recommendations for testing in addition to the required tests for HIV and HBV. FDA considers this alternative to be ineffective because it does not promote consistency in testing and related procedures among entities, does not provide FDA with clear enforcement authority, and is converse to the agency's and industry's mission, i.e., the safety of the blood supply. A second alternative would be to continue to specify in the regulations the marker to be tested for, such as a specific antigen or antibody. Tests for new or different markers of infection due to a communicable disease agent have changed as they become more appropriate or the technology in testing has become more sensitive or specific. FDA believes this alternative would not provide for the continued improvement in the testing regimen and would limit flexibility not only in testing, but in controlling cost to the different entities performing testing. Finally, FDA has requested industry comment and suggestions for alternatives to autologous unit testing, as discussed earlier under section '' C . Exceptions.''

V. The 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 (PRA) (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 this estimate is the time for reviewing the 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: Requirements for Testing Human Blood Donors for Evidence of Infection due to Communicable Disease Agents.

Description: FDA is proposing to revise the testing requirements in part 610 subpart E issued under the authorities of the act and the PHS Act. Currently, subpart E in part 610 requires testing for HBV and HIV and the development and administration of product quarantine and recipient notification (''Lookback'') program when donors test repeatedly reactive for antibody to HIV, or otherwise are determined to be unsuitable when tested in accordance with § 610.45. FDA is proposing to: (1) Require screening tests for evidence of infection due to communicable disease agents for autologous donations; (2) require supplemental (additional, more specific) testing of all repeatedly reactive screening test results for which there is a supplemental test; and (3) codify as requirements those recommendations that FDA has issued that are necessary to ensure blood safety, including testing for evidence of infection due to HIV, HBV, HCV, and HTLV.

FDA proposes to require that each donation of human blood or blood component, including those intended for autologous use or as a component of a medical device, be tested for evidence of infection due to HIV, types 1 and 2; HBV; HCV; and HTLV, types I and II. Each donation that tests repeatedly reactive when screened for evidence of infection due to any of the communicable disease agents would be required to be further tested whenever a supplemental (additional, more specific) test has been approved for such use by FDA. Testing would be required to be performed by a laboratory certified under CLIA and registered with FDA in accordance with part 607. Deferral of donors testing repeatedly reactive from future donations would be required. Criteria are proposed for release or shipment of human blood or blood components prior to completion of testing, and restrictions on use of human blood or blood components that test repeatedly reactive when screened for evidence of infection. The proposed rule would also require manufacturers of test kits approved to test human blood donors for evidence of infection due to communicable disease agents to verify an acceptable sensitivity and specificity of each lot of test kit using a reference panel obtained from CBER of other FDA designated source, when available.

Description of Respondents: Manufacturers of blood and blood components and clinical testing laboratories.

Based on June 1998 registration records, there are approximately 2,801 FDA registered blood collection facilities in the United States that collect approximately 27,000,000 units of Whole Blood and Source Plasma annually. To ensure consistency in the blood industry's testing practices, FDA is proposing to require testing consistent with its current recommendations and industry practice. Laboratories that perform testing of donor blood samples must be registered with FDA in accordance with part 607. Currently,

§ 607.65(g) provides an exemption from FDA registration to clinical laboratories that are approved for Medicare reimbursement and which are engaged in the testing of blood products in support of other registered establishments. FDA is proposing to remove this exemption and require such clinical labs to register. Because laboratories that currently perform testing of donor blood samples are already registered, FDA anticipates that the number of new registrants from clinical labs that will no longer be exempt from registration will be one or less per year. Under part 607 the burden for registrants not previously exempt is approved under OMB 0910–0052. Under that OMB package, FDA estimated the time required to prepare and send in the information for a new registration is approximately 1 hour.

FDA proposes to permit the emergency release or shipment of human blood or blood components prior to the completion of testing for evidence of infection due to communicable disease agents. The agency recognizes that there are rare medical emergencies, e.g., where a patient's need for blood is so acute as to preclude any communicable disease testing of the blood. FDA believes that the use of untested or incompletely tested blood in such medical emergencies should not be prohibited. FDA is proposing to remove § 640.2(f), which provides for emergency release of Whole Blood prior to completion of required testing and to place the provision for medical emergency situations in § 610.40(e), which will be applicable to all blood products, including Whole Blood. Release of blood or blood components due to a medical emergency prior to completion of required testing must be appropriately documented and the results of required testing provided to the consignees as soon as possible. Because such a medical emergency is a rare occurrence, FDA expects the recordkeeping and reporting burden to be very minimal with one or less occurrence per year. Documentation of the medical emergency should take a half hour or less and the reporting of test results to consignees is considered under section 1320.3(b)(2) of the PRA to be part of usual and customary practice or procedures to finish the testing and provide the results.

FDA is proposing in § 610.40(e) to permit, with FDA approval, shipment of certain blood components for further manufacturing before testing is completed and the test results are received by the collection facility. The only product currently shipped prior to completion of hepatitis B testing is a licensed product, Source Leukocytes, used in the manufacture of interferon, which requires rapid preparation from blood. Shipment of Source Leukocytes are preapproved under a product license application (and the shipment does not have to be reported to the agency). To obtain approval from FDA, the agency would expect the manufacturer(s) to submit specific procedures for collection, shipment, and quarantine of a product before testing is completed, completion of testing as soon as possible after shipping, and prompt communication of test results to the consignee. Based on the number of applications for the manufacture of Source Leukocytes received during fiscal year (FY) 95, FY 96, and FY 97, the agency anticipates two applications may be received annually. According to information from industry, a license application of this type would contain safety and effectiveness information and would take approximately 1,600 hours to prepare. FDA estimates that approximately 1 hour of the estimated 1,600 hours would be used in preparing the request for FDA's approval to ship a product prior to completion of testing.

According to information retrieved from FDA's database on licensed establishments, there are approximately 145 manufacturers producing licensed Source Leukocytes. Under § 610.40(e)(2), the agency estimates, based on information provided by industry, that each manufacturer would ship approximately three units of blood or blood components prior to testing the donor and that it would take an estimated 15 minutes to provide the completed test results to the consignee.

Under § 610.40(f)(2)(ii), according to FDA's database, there are approximately 343 licensed manufacturers that would ship known repeatedly reactive units. Industry estimates that each manufacturer would ship an estimated 10 units per month that would require two labels; one as repeatedly reactive for the appropriate screening test, and the other stating the exempted use specifically approved by FDA. Industry also estimates that it would take approximately 10 minutes per unit to affix the labels.

FDA estimates the burden for this collection of information as follows:

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
607.20	1	1	1	1	1
610.40(e)(2)	145	36	5,220	0.25	1,305
610.40(f)(2)(ii)	343	120	41,160	0.2	8,232
Total					9,538

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
610.40	1	1	1	1	1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Under section 1320.3(c)(2) of the PRA, the labeling requirements in 21 CFR 610.40(f)(2) and 610.42 do not constitute collection of information because information required to be on the labeling is originally supplied by the Federal Government to the manufacturers for the purpose of disclosure to the public in order to keep

the blood supply safe and protect public health.

The reporting of test results to the consignee in § 610.40(e) does not constitute collection of information burden because it is the customary and usual practice or procedure to finish the testing and provide the results to the manufacturer responsible for labeling the blood products.

In compliance with section 3507(d) of the PRA of 1995 (44 U.S.C. 3507(d)), the agency has submitted a copy of this proposed rule to OMB for review of the information collection provisions. Interested persons are requested to submit written comments regarding information collection by September 20, 1999 to the Office of Information and Regulatory Affairs, OMB (address above).

VI. Environmental Impact

The agency has determined under 21 CFR 25.31(j) that this action is of a type that does not individual or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Request for Comments

Interested persons may, on or before November 17, 1999, submit to the Dockets Management Branch (address above) written comments regarding this proposal, except that comments regarding information collection provisions should be submitted in accordance with the instructions in section V. of this document. Two copies of any comments on issues other than information collection are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VIII. 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. Wallace, E. L., W. H. Churchill, D. M. Surgenor, J. An, G. Cho, S. McGurk, and L. Murphy, ''Collection and Transfusion of Blood and Blood Components in the United States, 1992,'' *Transfusion*, 35, 802–812, 1995.

2. American Association of Blood Banks, *Facts About Blood and Blood Banking*, ''http://www.aabb.org/docs/facts.html''.

3. General Accounting Office, ''Blood Safety: Enhancing Safeguards Would Strengthen the Nation's Blood Supply,'' GAO–HEHS–97–143, June 1997.

4. AuBuchon, J. P., J. D. Birkmeyer, and M. P. Busch, ''Cost-effectiveness of Expanded Human Immunodeficiency Virus Testing Protocols for Donated Blood,'' *Transfusion*, 37:45–51, 1997.

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6. Lapane, K. L., A. F. Jakiche, D. Sugano, C. S. Wayne Weng, and W. D. Carey, ''Hepatitis C Infection Risk Analysis: Who Should Be Screened? Comparison of Multiple Screening Strategies Based on the National Hepatitis Surveillance Program,'' *The American Journal of Gastroenterology*, vol. 93, 4:591–596, 1998.

7. Tynell, E., S. Andersson, E. Lithander, M. Arneborn, J. Blomberg, H. Bertil Hansson, A. Krook, M. Nomberg, K. Ramstedt, A. Shanwell, and A. Bjorkman, ''Screening for Human T-Cell Leukaemia/Lymphoma Virus Among Blood Donors in Sweden: Cost Effectiveness Analysis,'' *British Medical Journal*, vol. 316, 1417–1422, May 1998.

8. Podnos, Y. D., and R. A. Williams, Current Risks for Blood Borne Viral Illness in Blood Transfusions, *Western Journal of Medicine*, vol. 168, 1:36–37, January 1998.

9. Myhre, B. A., and P. I. Figueroa, ''Infectious Disease Markers in Various Groups of Donors,'' *Annals of Clinical and Laboratory Science*, vol. 25, 1:39–43, 1995.

10. Public Health Service Inter-Agency Guidelines for Screening Donors of Blood, Plasma, Organs, Tissues, and Semen for Evidence of Hepatitis B and Hepatitis C, *Morbidity and Mortality Weekly Report* 40 (RR–4) April 19, 1991.

11. Margolis, H. S., P. J. Coleman, R. E. Brown, E. E. Mast, S. H. Sheingold, and J. A. Arevalo, ''Prevention of Hepatitis B Virus Transmission by Immunization: An Economic Analysis of Current Recommendations,'' *Journal of the American Medical Association*, vol. 274, No. 15, October 1995.

12. U.S. Centers for Disease Control and Prevention, 1997, ''www.cdc.gov/ncidod/diseases/hepatitis''.

13. *Morbidity and Mortality Weekly Report*, 40 (RR–4) April 19, 1991.

14. Kim, W. R., J. J. Poterucha, J. E. Hermans, T. M. Therneau, E. R. Dickson, R. W. Evans, and J. B. Gross, ''Cost-Effectiveness of 6 and 12 Months of Interferon Therapy for Chronic Hepatitis C,'' *Annals of Internal Medicine*, vol. 127, No. 10, November 1997.

15. Healthcare InfoSource, Inc., a subsidiary of the American Hospital Association, *Hospital Statistics*, 1998 Edition, Chicago, IL.

16. General Accounting Office, ''Blood Plasma Safety: Plasma Product Risks Are Low if Good Manufacturing Practices Are Followed,'' GAO–HEHS–98–205, September 1998.

17. American Association of Blood Banks (AABB) Association Bulletin No. 95–4: *AABB Position on Testing of Autologous Units. Attachment 1: AABA Anonymous Autologous Survey Request*, May 9, 1999.

List of Subjects

21 CFR Part 607

Blood.

21 CFR Parts 610 and 660

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 607, 610, 640, and 660 be amended as follows:

PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS

1. The authority citation for 21 CFR part 607 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371, 374; 42 U.S.C. 216, 262.

§ 607.65 [Amended]

2. Section 607.65 *Exemption for blood product establishments* is amended by removing paragraph (g).

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

3. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

4. The Table of Contents for subpart E of part 610 is revised to read as follows:

Subpart E—Testing Requirements for Communicable Disease Agents

Sec.
610.40 Test requirements.
610.41 Donor deferral.
610.42 Restrictions on use for further manufacture of in vitro diagnostic products.
610.44 Use of reference panels by manufacturers of test kits.
610.46 ''Lookback'' requirements.
610.47 ''Lookback'' notification requirements for transfusion services.

5. The heading of subpart E is revised to read as follows:

Subpart E—Testing Requirements for Communicable Disease Agents

6. Section 610.40 is revised to read as follows:

§ 610.40 Test requirements.

(a) *Human blood and blood components*. Except as specified in paragraph (b) of this section, each donation of human blood or blood components intended for use in preparing a product, including donations intended for autologous use or as a component of a medical device, shall be tested for evidence of infection due to the following communicable disease agents by using screening tests approved for such use by the Food and Drug Administration (FDA) in accordance with the manufacturer's instructions. One or more such tests shall be performed as necessary to adequately and appropriately reduce the risk of transmission of communicable disease.

(1) Human immunodeficiency virus, type 1;

(2) Human immunodeficiency virus, type 2;

(3) Hepatitis B virus;

(4) Hepatitis C virus;

(5) Human T-lymphotropic virus, type I;

(6) Human T-lymphotropic virus, type II.

(b) *Exceptions*. (1) Donations of Source Plasma are not required to be tested for evidence of infection due to the communicable disease agents listed in paragraphs (a)(5) and (a)(6) of this section.

(2) Donations of human blood or blood components intended solely as a component of an in vitro medical device are not required to be tested for evidence of infection due to the communicable disease agents listed in paragraphs (a)(5) and (a)(6) of this section unless they contain viable leukocytes.

(3) Requirements in this subpart shall not apply to the in-house use or distribution of samples of blood, blood components, plasma, or sera if intended for clinical laboratory testing or research purposes, and not for administration to humans or use in the manufacture of a product.

(c) *Further testing*. Each donation found to be repeatedly reactive by a screening test performed in accordance with paragraph (a) of this section shall be further tested whenever a supplemental (additional, more specific) test has been approved for such use by FDA.

(d) *Testing responsibility*. Testing for evidence of infection due to the communicable disease agents designated in paragraph (a) of this section shall be performed by a laboratory registered in accordance with part 607 of this chapter and certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) in accordance with 42 CFR part 493.

(e) *Release or shipment prior to testing*. Human blood or blood components that are required to be tested for evidence of infection due to the communicable disease agents designated in paragraph (a) of this section may be:

(1) Released for shipment or use before test results are available only in appropriately documented medical emergency situations; or

(2) Shipped for further manufacturing as approved in writing by FDA, provided the tests for evidence of infection due to communicable disease agents are performed as soon as possible after release or shipment and the results provided promptly to the consignee.

(f) *Restrictions on shipment or use*. (1) Human blood or blood components that have a repeatedly reactive screening test for evidence of infection due to a communicable disease agent(s) designated in paragraph (a) of this section or that are collected from a donor with a record of a repeatedly reactive screening test for evidence of infection due to a communicable disease agent designated in paragraph (a) of this section shall not be shipped or used, except as provided in paragraph (f)(2) or (f)(3) of this section.

(2) The restrictions shall not apply to:

(i) Blood or blood components intended for autologous use, provided that such units shall be appropriately labeled in accordance with § 606.121(i) of this chapter and with the following Biohazard legend:

BIOHAZARD

(ii) Blood or blood components may be shipped or used under conditions specifically approved in writing by FDA, provided that such blood or blood components are appropriately labeled in accordance with § 606.121 or § 640.70 of this chapter and display the Biohazard legend. Such blood or blood components shall be labeled as repeatedly reactive for the appropriate screening test for evidence of infection due to the identified communicable disease agent. For blood or blood components intended for further manufacturing into injectable products, labeling shall include a statement indicating the exempted use specifically approved by FDA. For blood or blood components intended for in vitro use, labeling shall include the statement ''Caution: For Further Manufacturing Into Non-Injectable Products For Which There Are No Alternative Sources''.

(iii) Samples for in-house use or distribution if intended for clinical laboratory testing or research purposes, and not intended for administration in humans or use in the manufacture of a product.

(3) Human blood or blood components testing negative for evidence of infection due to a communicable disease agent(s) designated in paragraph (a) of this section from a donor with a record of a repeatedly reactive result for the same screening test for evidence of infection due to a communicable disease agent(s) designated in paragraph (a) of this section may be used if the donor has been subsequently shown to be suitable by a requalification method or process found acceptable for such purposes by FDA.

7. Section 610.41 is revised to read as follows:

§ 610.41 Donor deferral.

Except for autologous donors and as provided in § 640.65(b)(2)(ii), (b)(2)(iii), and (b)(2)(iv) of this chapter, donors testing repeatedly reactive for evidence of infection due to a communicable disease agent(s) listed in § 610.40(a) or reactive for a serologic test for syphilis shall be deferred from future donations of blood and blood components except:

(a) Donors who test repeatedly reactive for HTLV, types I or II, or anti-HBc on only one occasion, unless further tested under § 610.40(c).

(b) Donors testing repeatedly reactive for HTLV, types I and II or anti-HBc may serve as donors of Source Plasma.

(c)(1) Deferred donors testing repeatedly reactive for evidence of infection due to a communicable disease agent listed in § 610.40(a) may serve as donors for blood or blood components when used in accordance with § 610.40(f).

(2) Deferred donors previously showing evidence of infection due to hepatitis B virus when tested in accordance with § 610.40(a) and (c) may

donate blood or blood components for use as a component of a medical device or may donate blood or blood components in the preparation of Hepatitis B Immune Globulin (Human) provided their current donations test nonreactive when tested in accordance with § 610.40(a) and the donor is otherwise determined to be suitable.

(d) Donors with a reactive serologic test for syphilis need not be deferred if found negative by an approved specific treponemal test (confirmatory test for syphilis).

(e) Deferred donors may be found to be suitable as donors of blood or blood components by a method or process found acceptable for such purposes by the Food and Drug Administration.

8. Section 610.42 is added to subpart E to read as follows:

§ 610.42 Restrictions on use for further manufacture of in vitro diagnostic products.

In vitro diagnostic products manufactured from human blood or blood components found to be repeatedly reactive by a screening test performed in accordance with § 610.40(a) shall be labeled in accordance with § 809.10 of this chapter, and shall include a statement of warnings in the label indicating that the product was manufactured from a donation found to be repeatedly reactive by a screening test for evidence of infection due to the identified communicable disease agent.

9. Section 610.44 is added to subpart E to read as follows:

§ 610.44 Use of reference panels by manufacturers of test kits.

When available, a reference panel shall be obtained from the Center for Biologics Evaluation and Research or from a Food and Drug Administration designated source, and shall be used by the manufacturer to verify acceptable sensitivity and specificity of:

(a) Each lot of a test kit approved for use in testing donations of human blood and blood components for evidence of infection due to communicable disease agents listed in § 610.40(a); and

(b) Each lot of a human immunodeficiency virus (HIV) test approved for use in the diagnosis or monitoring of this communicable disease agent. A lot that is found to be not acceptable for sensitivity and specificity under § 610.44(a) and (b) shall not be released.

§ 610.45 [Removed]

10. Section 610.45 *Human Immunodeficiency Virus (HIV) requirements* is removed.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

11. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 640.2 [Amended]

12. Section 640.2 *General requirements* is amended by removing paragraph (f).

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

13. The authority citation for 21 CFR part 660 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 660.42 [Removed]

14. Section 660.42 *Reference panel* is removed.

Dated: April 20, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 99–21296 Filed 8–18–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606 and 630

[Docket No. 98N–0607]

General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require blood and plasma establishments to notify donors of their deferral due to test results for communicable disease agents or failure to satisfy suitability criteria with the intent of reducing the risk of transmission of communicable disease through the use of blood, blood components, and blood derivatives. Under the proposed rule, blood and plasma establishments would notify the donors that they have been deferred and the reason for the deferral; provide information concerning appropriate medical followup and counseling; describe the types of donations the donors should not make in the future; and discuss the possibility that the donor may be found suitable in the future, where appropriate. FDA is issuing this rule as part of the agency's ''Blood Initiative'' in which FDA is reviewing and, when appropriate, revising its regulations, policies, guidance, and procedures related to blood and blood products, including blood derivatives.

DATES: Submit written comments by November 17, 1999. Submit written comments on the information collection provisions by September 20, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. 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., Washington, DC 20503, Attention: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Introduction

For a variety of reasons discussed as follows, FDA has decided to comprehensively review and, as necessary, revise its regulations, policies, guidance, and procedures related to the licensing and regulation of blood products. In the **Federal Register** of June 3, 1994 (59 FR 28821 and 59 FR 28822, respectively), FDA issued two documents entitled ''Review of General Biologics and Licensing Regulations'' (Docket No. 94N–0066) and ''Review of Regulations for Blood Establishments and Blood Products'' (Docket No. 94N–0080). The documents announced the agency's intent to review biologics regulations (parts 600, 601, 606, 607, 610, 640 and 660 (21 CFR 600, 601, 606, 607, 610, 640 and 660)), and requested written comments from the public. Interested persons were given until August 17, 1994, to respond to the documents. In response to requests for additional time, FDA twice extended the comment period, as announced in the **Federal Register** of August 17, 1994

(59 FR 42193), and November 14, 1994 (59 FR 56448). In addition, FDA responded to requests for a public meeting to allow for the presentation of comments regarding the agency's intent to review the biologics regulations. On January 26, 1995, FDA held a public meeting to provide an opportunity for all interested individuals to present their comments and to assist the agency in determining whether the regulations should be revised, rescinded, or continued without change. Since the time of the regulation review, FDA has implemented a number of changes to its regulations and policies applicable to the general biologics and licensing regulations, some of which have applied to blood products as well as other biological products. (See, e.g., the final rules issued May 14, 1996 (61 FR 24313); August 1, 1996 (61 FR 40153); November 6, 1996 (61 FR 57328); July 24, 1997 (62 FR 39890); and October 15, 1997 (62 FR 53536)).

Because of the importance of a safe national blood supply, the U. S. House of Representatives Committee on Government Reform and Oversight, Subcommittee on Human Resources and Intergovernmental Relations (the Subcommittee) and other groups such as the General Accounting Office (GAO), and the Institute of Medicine (IOM) have reviewed the agency's policies, practices, and regulations. Reports issued following the respective reviews made a number of recommendations as to how FDA might improve the biologics regulations, particularly as they apply to the continued safety of blood products. The relevant reports are: (1) ''Protecting the Nation's Blood Supply From Infectious Agents: The Need for New Standards to Meet New Threats,'' by the Subcommittee (August 2, 1996); (2) ''Blood Supply: FDA Oversight and Remaining Issues of Safety,'' by GAO (February 25, 1997); (3) ''Blood Supply: Transfusion-Associated Risk,'' by GAO (February 25, 1997); and (4) ''HIV and the Blood Supply: An Analysis of Crisis Decisionmaking,'' by IOM (July 13, 1995). These reports are on file with the Dockets Management Branch (address above) under the docket number given in the heading of this document.

FDA has reviewed these reports and agrees with the majority of the recommendations contained within them. However, rather than to only respond specifically to the recommendations from the Subcommittee, GAO, IOM, and the public, FDA has convened a number of internal task forces to review a variety of issues related to the regulation of blood and blood products, including how to most appropriately update the existing regulations applicable to blood and blood products. In the future, FDA intends to issue a number of blood-related rulemakings that various FDA task groups are currently preparing. FDA is not describing the specific recommendations it has received and the numerous objectives of the Blood Initiative in this document. Future rulemaking and other notices will describe and discuss specific recommendations and regulatory objectives.

II. Background on Notification of Deferred Donors

This rule is proposed in order to reduce the risk of infection due to communicable disease agents to blood product recipients and to individuals handling blood or blood products. The safety of the blood supply is enhanced when donors who may present significant risks of transmitting infectious disease, because of testing results indicating evidence of infection due to communicable disease agents or failure to satisfy suitability criteria associated with the prevention of certain communicable disease agents, are excluded from donating blood and blood components. FDA has issued regulations at parts 610 and 640 on donor testing and suitability in order to help assure the safety of blood products. The Public Health Service (PHS) and FDA, as part of PHS, also have periodically issued guidance on donor testing, suitability, deferral, and notification when new scientific developments warranted. This rule is also being proposed so that donors may be informed of their deferral and seek medical counseling or treatment, if appropriate. Additionally, such notification is expected to improve blood safety by preventing re-donation by individuals at risk for transmitting infectious disease. Also, precautions taken to minimize the risk of transmission by informed donors may reduce the spread of communicable diseases in the population.

FDA has taken a number of actions to provide for the notification of certain deferred donors. Described in the following paragraphs are some of the more significant actions and their impact on donor notification.

In 1983, PHS issued guidelines recommending that individuals at increased risk for Acquired Immune Deficiency Syndrome (AIDS) refrain from donating (Ref. 1).

In 1985, PHS issued guidelines concurrent with the approval of human immunodeficiency virus (HIV) antibody tests that donors testing repeatedly reactive in screening tests for human immunodeficiency virus, type 1 (HIV–1) be notified. In addition, PHS recommended that the donor be notified if other tests such as the Western blot were positive (Ref. 2).

In 1987, PHS recommended that a person be considered to have serologic evidence of HIV infection only after an enzyme immunoassay screening test was repeatedly reactive and another test such as Western blot had been performed to validate the results (Ref. 3). These recommendations have been updated periodically (Refs. 4 and 5) and extended to include notification of donors testing positive for antibody to human immunodeficiency virus, type 2 (HIV–2) (Ref. 6).

In its 1990 recommendations, FDA recommended to blood establishments that supplemental testing be performed prior to donor notification in its Memorandum to Blood Establishments: Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products.

In 1988, PHS recommended notification of donors who were confirmed positive for human T-lymphotropic virus, type I (HTLV–I) of their test results and that they had been deferred as a donor in Licensure of Screening Tests for Antibody to T-Lymphotropic Virus, Type I (Ref. 7).

In 1991, the Department of Health and Human Services (DHHS), in a PHS Inter-Agency Guideline, recommended notifying donors of the results of tests for hepatitis B surface antigen (HBsAg), antibody to hepatitis C virus (anti-HCV), alanine aminotransferase (ALT) and antibody to hepatitis B core (anti-HBc) in the Public Health Service Interagency Guideline for Screening Donors of Blood, Plasma, Organs, Tissue and Semen for Evidence of Hepatitis B and Hepatitis C (Ref. 8).

In the 1995 Guideline for Quality Assurance in Blood Establishments (60 FR 36290, July 14, 1995), FDA further identified donor notification and counseling as two of the five key elements of donor deferral.

The blood industry has adopted these recommendations as well as developed their own guidance on donor notification. Industry practice includes notifying donors who are permanently deferred due to positive test results for viral markers of their deferred status and providing recommendations for followup testing, counseling, and appropriate medical referral. In the past, however, FDA has not issued regulations on when a deferred donor should be notified. To further enhance the safety of the blood supply, FDA

believes that donors should be notified when they are deferred due to test results or donor suitability criteria. Accordingly, FDA is proposing to require notification of donors who are deferred for evidence of infection due to communicable disease agents as required under proposed § 610.41 and for failure to satisfy suitability criteria associated with the prevention of communicable diseases. The proposed rule would help assure consistency in the blood industry's notification practices, and would provide FDA with clear enforcement authority if compliance problems occur.

GAO, at the request of Congressman John Dingell, Ranking Minority Member, Committee on Commerce, House of Representatives, recently reviewed the FDA's ''layers of safety'' intended to help ensure the safety of blood products in order ''to identify issues that might threaten the nation's blood supply.'' In its report of February 1997 entitled ''Blood Supply: Transfusion Associated Risks,'' GAO concluded that ''the blood supply is safer today than at any time in recent history.'' Nevertheless, in an accompanying report (''Blood Supply: FDA Oversight and Remaining Issues of Safety''), GAO made several recommendations on improving the safety of our nation's blood supply. GAO recommended that ''(FDA) require blood facilities to notify all donors who are permanently deferred that they have been deferred and the medical reason they are deferred.'' Citing public health concerns, GAO further recommended that:

> * * * (N)otification be based on positive confirmatory tests for viral markers (for the viruses that have licensed confirmatory tests) and all other medical reasons that result in permanent deferral (for example, the intake of pituitary growth hormone). Notification should include the reason for the permanent deferral, possibilities for re-entry as a donor, and counseling or referral to the donor's physician (including, when pertinent, actions to be taken to minimize transmission of viruses to others).

In its response, DHHS generally agreed with the GAO recommendations. FDA believes the proposed donor notification rule would enhance blood safety by promoting self-exclusion of donors who may present significant risks to the blood supply. FDA believes that donors who are informed of and understand the significance of their deferred status are less likely to attempt to donate again, thus helping to assure a safer blood supply. Donor notification also would enhance the public health by informing donors, as appropriate, of the need to seek treatment and additional medical counseling. Such measures could benefit the health of the donor and also provide information needed to prevent further spread of infection.

III. The Impact of Other Proposed Rules

FDA intends to issue other proposed rules in conjunction with the proposed donor notification rule. FDA is proposing to revise the donor testing and deferral regulations in part 610, which apply to blood and blood components. The related proposed testing and deferral document is found elsewhere in this issue of the **Federal Register**. FDA also intends to issue in the near future a proposed rule to revise donor suitability requirements.

The related proposed testing and deferral rule would, among other things, add requirements to test blood and blood components for evidence of infection due to hepatitis C virus (HCV), HTLV–I, and HTLV–II, while retaining testing requirements for hepatitis B virus (HBV), HIV–1, and HIV–2. FDA intends that the proposed testing rule would replace the requirements currently found in §§ 610.40 through 610.45. The testing and deferral requirements for a serologic test for syphilis (i.e., evidence of infection due to *Treponema pallidum*) found in §§ 640.5 and 640.65 would remain in part 640. The related proposed testing and deferral rule also would add a requirement in proposed § 610.41 that, except in certain specified circumstances, donors testing repeatedly reactive for evidence of infection due to a communicable disease agent(s) listed in proposed § 610.40(a) be deferred from future donations of blood or blood components. In addition, donors testing reactive for a serologic test for syphilis would also be deferred except as provided in current § 640.65 or proposed § 610.41. Under the proposed donor notification rule, blood and plasma establishments would be required to notify donors who have been deferred under proposed § 610.41.

As mentioned previously, FDA also intends to propose to revise the donor suitability requirements for donors of blood and blood components. FDA intends to identify donor suitability criteria that would cause a donor to be deferred and thus trigger notification under the proposed donor notification document. Among those donor suitability criteria being considered are high risk behavior associated with the transmission of HIV, HBV, and HCV, such as past or present abuse of injectable drugs. A new section identifying donor suitability criteria will be designated in the final rule for donor notification.

IV. Legal Authority

FDA is proposing to issue this new rule under the authority of sections 351 and 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 262 and 264 *et seq.*) and the provisions of the Federal Food, Drug, and Cosmetic Act (the act) that apply to drugs (21 U.S.C. 201 *et seq.*). Under section 361 of the PHS Act, FDA may make and enforce regulations necessary to prevent the introduction, transmission, and spread of communicable disease between the States or from foreign countries into the States (see Sec. I, 1966 Reorg. Plan No. 3 at 42 U.S.C. 202 for delegation of section 361 authority from the Surgeon General to the Secretary of the Department of Health and Human Services (Secretary); see 21 CFR 510.(a)(4) for delegation from the Secretary to the Food and Drug Administration). Intrastate transactions may also be regulated under section 361 of the PHS Act (see *Louisiana* v. *Mathew*, 427 F. Supp. 174, 176 (E.D.La. 1977)).

Notification of donors that they have been deferred and consequently should not attempt subsequent donations would help prevent unsafe units of blood or blood products from entering the blood supply. The proposed rule targets those donors who may present significant risks of infectious agents; thus, it works directly to prevent the introduction and spread of communicable disease. Moreover, the proposed rule is designed to help ensure that risks of transmitting infectious disease are excluded from the pool of eligible donors. FDA relies on a system of overlapping layers of safety to ensure the safety of the nation's blood products. One of the important layers of safety is the self-exclusion of donors because of high-risk behaviors associated with the risk of HIV, or hepatitis B and C, or signs and symptoms of AIDS and hepatitis. A second crucial layer of safety is the system of donor deferral registries designed to eliminate unsuitable donors from the donor population. Notification of donors who are deferred adds to the protection provided by donor deferral registries by making deferred donors aware that they should not attempt to donate again. Consequently, the screening of unsuitable donors provided by the registries is enhanced by the self-exclusion of donors who have been made aware of their status and the risks their donation may present to the blood supply.

The proposed notification rule also would protect the health of the deferred donor by assuring that the individual is

aware he or she may need further medical evaluation including testing, treatment, and counseling. As FDA has previously made clear ''(i)n an indirect but no less important manner, the requirements of donor protection assure * * * that there will be a continuous and healthy donor population'' (Additional Standards for Human Blood and Blood Products (41 FR 10762, March 12, 1976)).

FDA's license revocation regulations provide for the initiation of revocation proceedings, among other reasons, if the establishment or the product fails to conform to the standards in the license application or in the regulations designed to ensure the continued safety, purity, or potency of the product (§ 601.5). Section 351 of the PHS Act also provides for criminal penalties for violation of the laws governing biologics. Violations can be punishable by fines or imprisonment, or both.

The act also applies to biological products (42 U.S.C. 262(d)), as amended. Blood and blood components are considered drugs, as that term is defined in section 201(g)(1) of the act (21 U.S.C. 321(g)(1)) (see *United States* v. *Calise*, 217 F. Supp. 705 (S.D.N.Y. 1962)). Because blood and blood components are drugs under the act, blood and plasma establishments must comply with the substantive provisions and related regulatory scheme of the act. Under section 501(a)(2)(B) of the act, drugs are deemed ''adulterated'' if the methods used in their manufacturing, processing, packing, or holding do not conform with current good manufacturing practices (CGMP's) (21 U.S.C. 351(a)(2)(B)). Under the proposed donor notification rule, blood and plasma establishments would be required to develop standard operating procedures (SOP's) for notifying deferred donors. A blood or plasma establishment that failed to comply with donor notification procedures would violate CGMP's and, therefore, would be subject to the act's enforcement provisions.

V. Description of the Proposed Rule

FDA is proposing to create a new part 630, General Requirements for Blood, Blood Components, and Blood Derivatives. This part would include the following: (1) Consolidation of the criteria to be used when determining suitability of donors of human blood and blood components; (2) requirements for donor deferral from future donation when a donor fails to satisfy the suitability criteria; and (3) requirements for donor notification and the reason for their deferral due to donor test results or failure to satisfy suitability criteria. Donor suitability criteria and donor deferral are not the subject of this proposed rule. These proposed requirements will be addressed in a rulemaking to be published in the near future. As necessary, FDA may add other requirements applicable to blood products in the future. The focus of this proposed rulemaking would be to require donor notification when the donor is deferred due to testing results or failure to meet donor suitability criteria and to provide the reason for the deferral.

The proposed rule would require blood and plasma establishments to notify donors who are deferred in accordance with proposed § 610.41 or for failure to satisfy donor suitability criteria that they have been deferred as donors and the reason for their deferral. Deferred donors would be informed, as appropriate, that they should not donate blood or blood components in the future. Donors would also be informed about the need for additional counseling and medical evaluation, as appropriate. Under the proposed rule, blood and plasma establishments would be required to develop SOP's for deferring donors and notifying deferred donors. FDA is not proposing to require blood and plasma establishments to notify donors who the blood or plasma establishments may defer voluntarily for a variety of medical reasons beyond the requirements in proposed § 610.41 and donor suitability criteria associated with the prevention of communicable diseases. FDA recognizes that blood and plasma establishments would need to exercise medical judgment in determining which donors to defer voluntarily and whether to notify such donors. PHS and FDA may periodically issue recommendations on testing, deferral, and notification of donors who may be at risk of infectious disease.

Donors whose blood or blood components test repeatedly reactive for evidence of infection due to a communicable disease agent for which testing would be required by FDA under proposed § 610.40, or as specified for syphilis in current §§ 640.5 or 640.65, would be deferred in accordance with proposed § 610.41. Blood and plasma establishments would notify such deferred donors under the proposed notification rule that they have been deferred, and the reason for their deferral including their screening test results and the results of any approved supplemental (i.e., additional, more specific) tests that were performed. FDA currently requires that supplemental testing for both HIV–1 and HIV–2 antibodies be performed under § 610.46. PHS and FDA have recommended that HIV notification should occur after the results of the approved supplemental testing are available. Results of supplemental tests are useful in providing additional information for purposes of medical followup and counseling. Therefore, FDA is proposing that blood establishments attempt to obtain the results of supplemental testing proposed under § 610.40(c) prior to notifying donors of their deferral. FDA has included a maximum time period of 8 weeks to notify the donor. If notification occurs prior to receipt of the supplemental test results, blood establishments would be required to renotify the donors with the results of the supplemental testing.

Blood and plasma establishments would be required to notify deferred donors where appropriate, of the possibility for re-entry as donors of blood and blood components if they are found to be suitable using methods or processes approved by FDA in accordance with proposed § 610.41 or current § 640.65, provided that the donor meets all other requirements.

Under § 610.40 of the proposed testing rule, blood and plasma establishments would be required to test blood and blood components, including autologous donations, for evidence of infection due to HIV–1, HIV–2, HBV, HCV, HTLV–I, and HTLV–II using FDA approved tests. Donors whose donations test repeatedly reactive for evidence of those agents required under proposed § 610.40(a) or for syphilis under current §§ 640.5 and 640.65 would be deferred in accordance with proposed § 610.41. This proposed donor notification rule would require that blood and plasma establishments notify the deferred donor of their deferral and of their test results.

In the related proposed § 610.41, FDA is proposing several exceptions to donor deferral that also have an impact on donor notification. Autologous donors testing repeatedly reactive for communicable disease agents would not be deferred. Blood establishments would not be required under this proposed rule to notify autologous donors who test repeatedly reactive for communicable disease agents under proposed § 610.40(a). Nevertheless, FDA recommends that blood establishments notify autologous donors of repeatedly reactive test results and supplemental test results, when applicable, for the purpose of medical followup and counseling. FDA specifically is requesting comments on whether to require notification of autologous donors of repeatedly reactive and supplemental test results even though such donors would not be deferred.

In the related proposed § 610.41(a), donors who test repeatedly reactive for HTLV, types I and II, or anti-HBc on only one occasion, would be permitted to donate again without being deferred from further donation unless there is further testing using an approved supplemental (additional, more specific) test. Should licensed supplemental tests for HTLV, types I and II be approved, donors would be required to be deferred after only a single repeatedly reactive donation similar to most other screening tests. It is FDA's expectation that donor re-entry algorithms would become feasible at that time. However, until such time, upon testing repeatedly reactive a second time for HTLV, types I and II or anti-HBc, the donor would be deferred. Blood establishments would be required to notify donors that they have been deferred from donations of Whole Blood, and transfusable components (including Plasma) only after they had tested repeatedly reactive a second time for HTLV, types I and II or anti-HBc. FDA specifically requests comments on whether to notify donors who test repeatedly reactive for HTLV, types I and II or anti-HBc on only one occasion or to wait to notify donors upon testing repeatedly reactive the second time. Upon the availability of an approved supplemental (additional, more specific) test, a repeatedly reactive donor would be deferred after a single repeatedly reactive donation. At such time, blood establishments would notify donors of the test results of both the approved screening and supplemental tests. As appropriate, blood establishments would notify such deferred donors that they may be eligible for re-entry if determined to be suitable by a method or process approved by FDA in accordance with proposed § 610.41.

In related § 610.41(b), FDA is proposing to except from deferral donors testing repeatedly reactive for HTLV, types I and II, or anti-HBc as donors of Source Plasma. However, the agency is requesting comments in the proposed rule ''Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents'' (hereinafter the ''proposed rule on donor testing'') on permitting such donors to donate Source Plasma to be used in the manufacture of plasma derivatives as it relates to the exposure to other possible risks, such as through the association of HTLV infection with abuse of intravenous drugs. The agency also includes in the proposed rule on donor testing a discussion on the risk of transmitting HTLV, types I and II.

Related proposed § 610.41(c)(1) would permit deferred donors to donate blood and blood components used in accordance with proposed § 610.40(f). In related proposed § 610.40(f), the agency would require that blood and blood components that test repeatedly reactive when screened for evidence of infection due to communicable disease agents listed in proposed § 610.40(a) would not be shipped or used except for autologous use or for purposes or under conditions approved in writing by FDA. Blood and plasma establishments that collect blood or blood components under conditions approved under proposed § 610.40(f)(2)(ii) or current § 640.65 could notify donors deferred under proposed § 610.41 or current § 640.65 that they would be eligible to donate blood or blood components, as appropriate, for use as a component of an in vitro device or for other approved uses.

In related § 610.41(c)(2), the agency is proposing to restrict the use of blood or blood components from donors showing previous evidence of infection due to hepatitis B virus when tested in accordance with proposed § 610.40(a) and (c). Such blood and blood components may be approved for use only as a source of antibody to hepatitis B surface antigen for the preparation of Hepatitis B Immune Globulin (Human) or as a component of a medical device. Donors with previous evidence of infection with hepatitis B when tested in accordance with proposed § 610.40(a) and (c) may serve as donors of a component of a medical device or as donors of Source Plasma for use as a source of antibody to hepatitis B surface antigen for the preparation of Hepatitis B Immune Globulin (Human). In the proposed rule on donor testing, the agency has requested comments on the use of vaccinated donors for HBV as an alternative to using donors previously showing evidence of infection due to hepatitis B virus in the preparation of Hepatitis B Immune Globulin (Human) provided their current donations test nonreactive when tested in accordance with proposed § 610.40(a) and the donor is otherwise determined to be suitable. Blood and plasma establishments that are approved to collect Source Plasma from such donors under proposed § 610.40(f) could notify deferred donors that they may donate for such purposes.

In related proposed § 610.41, the agency is proposing to defer donors who test reactive for a serologic test for syphilis except as provided under current § 640.65. In related proposed § 610.41(d), the agency would exempt from deferral donors who test reactive on a serologic test for syphilis provided the donor is found negative by an approved specific treponemal test (confirmatory test for syphilis). Blood and plasma establishments would notify all other donors who test reactive for evidence of syphilis that they have been deferred and of the results of tests including the result of the approved specific treponemal tests. However, as FDA has noted in the preamble to the related proposed rule on donor testing, there is ongoing debate in the scientific community as to the continuing need for a testing requirement for the serological test for syphilis. Therefore, the proposal to defer donors who test reactive for syphilis is subject to change pending the outcome of the request for comments on the value of donor testing for syphilis in the proposed rule on donor testing.

The proposed rule also would require blood and plasma establishments to notify donors who have been deferred because of donor suitability criteria. FDA intends to create in future rulemaking a new section identifying certain donor suitability criteria which are intended to reduce the risk of communicable disease agents that would result in deferral of the donor and require donor notification. Among those donor suitability criteria being considered are high risk behavior associated with the transmission of HIV, HBV, and HCV, such as past or present abuse of injectable drugs. Blood and plasma establishments would notify deferred donors of their deferral and advise them to seek further testing or medical counseling, as appropriate.

Under the proposed rule, blood and plasma establishments would be required to provide information to deferred donors concerning appropriate medical followup and counseling. FDA currently recommends that this information include disease associations and possible modes of transmission as well as actions to be taken to minimize the risk of transmission. FDA believes that such information also would include referral to their own physician, or, where appropriate, the location of public health clinics as well as alternative testing and counseling centers. Blood and plasma establishments should consult current PHS Guidelines and FDA recommendations for more detailed recommendations on the content of donor notification.

A. Timeframe for Notification.

Under § 630.6(c) of the proposed rule, blood and plasma establishments would be required to notify donors within 8 weeks after determining that the donor should be deferred. In many instances

arising under the proposed rule, blood and plasma establishments would be able to fulfill the notification requirements onsite. For example, a donor who is deferred because of donor suitability criteria can be notified at the time of the donor interview or at the first return visit after the information is available, if within 8 weeks. Blood and plasma establishments would be required to have SOP's addressing donor deferral and notification and keep documentation on all deferrals as well as any resulting notification. Some blood and plasma establishments may notify deferred donors by registered mail, return receipt; or may choose to request that the donor return for direct donor notification, so long as notification of deferral occurred within the 8-week period. FDA requests comments on (1) methods of notification that would help assure adequate donor confidentiality and (2) the current application and sufficiency of Federal, State, and local laws that protect the privacy of the individual being notified. FDA believes that at least three attempts should be made within an 8-week period. In all cases, blood and plasma establishments should document their attempts to notify donors and maintain a record of these attempts or of the basis for discontinuing the effort to notify deferred donors.

B. Other Requirements.

Donor notification should be conducted by trained personnel in accordance with the requirements in § 606.20. Blood and plasma establishments would be required to revise their SOP's to include procedures for notification of deferred donors. For the purposes of notification under the proposed rule, blood and plasma establishments would be required to maintain records of the donor's permanent address. Donors should provide proof of a permanent, fixed address. Individuals who do not have evidence of a current address or who merely provide an address of a known or obviously transient nature should not be accepted as donors.

VI. Analysis of Impacts and Initial Regulatory Flexibility Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Public Law 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). The Regulatory Flexibility Act requires agencies to analyze whether a rule may have a significant impact on a substantial number of small entities and, if it does, to analyze regulatory options that would minimize the impact. Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

OMB has determined that the proposed rule is is a significant regulatory action as defined by the Executive Order and so is subject to review. Because the rule does not impose any mandates on State, local, or tribal governments, or the private sector, that will result in any 1 year of $100 million or more, FDA is not required to perform a cost-benefit analysis according to the Unfunded Mandate Reform Act.

The Regulatory Flexibility Act requires agencies to prepare a Regulatory Flexibility Analysis for each rule unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As explained in the following sections of this document, the proposed rule is not expected to have a significant economic impact on a substantial number of small business entities because donor deferral and notification are considered usual and customary business for the affected entities.

A. Objectives and Basis of the Proposed Action

As discussed previously, FDA is considering the proposed action for the purpose of reducing the risk of infection due to communicable disease agents to blood recipients and to individuals handling blood or blood products. The safety of the nation's blood supply is enhanced when donors whose test results indicate evidence of infection due to communicable disease agents or fail to satisfy suitability criteria associated with the prevention of certain communicable disease agents are excluded from donating blood and blood components. Once donors are deferred from donation, such donors would be informed of their deferral and the reason, and advised to seek medical counseling or treatment, as appropriate. Public health would be protected not only by deferring the donor from future donations and preventing the transmission of communicable disease agents through transfusion, but also by counseling the donor in precautions to minimize the risk of transmitting the disease to others in daily life.

This action is taken under the authority of sections 351 and 361 of the PHS Act and section 501 of the act to prevent the introduction, transmission, and spread of communicable disease, and to ensure that methods used in manufacturing conform with CGMP's. Failure to comply with donor notification procedures would violate CGMP's and, therefore, would be subject to the act's enforcement provisions. FDA has reviewed related Federal rules and has not identified any rules that duplicate, overlap, or conflict with the proposed rule.

B. Nature of the Impact

The proposed rule requires that blood establishments notify deferred donors of their deferral based on either suitability criteria included in the donor screening interview or because of the results of testing for evidence of infection due to disease agents including HIV, HTLV, hepatitis B, or hepatitis C. Under the proposed rule, the donor must be notified that he or she has been deferred, and the reason for deferral. The deferred donor must also be notified of the types of blood or blood components that should not be donated in the future. The notification must also include the results of tests for evidence of infection due to communicable disease including supplemental test results, information concerning appropriate medical followup and counseling, and when applicable, the possibility that the donor may be found suitable for future donations. The donor notification process must include three attempts of notification, completed within 8 weeks of the determination of the donor deferral. In order to implement this notification process, the proposed rule also requires that blood establishments obtain a permanent address for each prospective donor. The establishment must also maintain records of its attempts to notify a deferred donor within the prescribed timeframe.

C. Type and Number of Entities Affected

The proposed deferred donor notification requirements will affect all blood and plasma establishments that collect blood and blood components from allogeneic donors. FDA's Office of Blood Research and Review (OBRR) has record of 2,801 registered blood and plasma establishments, including 487

plasma centers and 2,314 blood centers. The American Association of Blood Banks (AABB) estimates that approximately 14 million blood donations are collected annually. Allogeneic blood donations have recently accounted for an estimated 87.2 percent of that total (Ref. 9). In 1997, GAO estimated that approximately 12 million donations of source plasma were collected by plasma centers (Ref. 10).

D. Estimated Impact of Proposed Requirements for Deferred Donor Notification

The proposed rule is expected to have a minor net impact on blood establishments because the blood industry has already generally implemented deferred donor notification; virtually all establishments include this process within current operational guidelines. FDA expects that the primary impacts of the proposed rule will include a one-time review effort at each facility and a more extensive notification process at those facilities that currently perform deferred donor notification over a longer timeframe or with fewer followup attempts than specified in the rule.

The one-time effort to review and modify current SOP's is expected to vary among establishments depending on the extensiveness of a facility's current protocols for deferred donor notification. For establishments that already keep required donor information and perform the level of notification effort specified by the rule, FDA estimates that it would take approximately 4 hours of staff time to reconcile the proposed regulations against the facility's current standards. This process could be performed by a technical specialist who acts as a regulatory reviewer or manager of quality assurance. Based on the total average hourly compensation of $25.67 for professional specialty and technical occupations in the health services industry, as reported by the Bureau of Labor Statistics for March 1997, the cost would be approximately $103 per facility. For establishments that already perform donor deferral notification but information provided to deferred donors or other aspects of the notification process are not the same as specified in the proposed rule, FDA assumes that approximately 24 hours of staff time would be required to align current SOP's and donor recordkeeping with the provisions of the rule. The cost in this case would be approximately $616 per facility. FDA does not have the data to estimate the percentage of facilities that will require a minimal effort versus a more involved review of SOP's; however, it is expected that many facilities have SOP's and recordkeeping standards that are consistent with the rule. Assuming a minimal review is needed at two-thirds of the currently operating establishments, and a more extensive review is conducted by the others, the total one-time cost for the blood and plasma industries is estimated to be $762,158.

The yearly increase in cost is based on the ongoing notification of deferred donors. FDA assumes that all donors deferred based on the screening interview can be notified onsite at the time of deferral, and provided with the proposed information. FDA assumes that this will introduce no new costs for the blood and plasma establishments. The cost of notifying donors deferred on the basis of blood test findings is based on a proportional extrapolation of the number of donors who would test repeatedly reactive for evidence of infection in tests for HIV, HTLV, HBV, or HCV, and have positive findings in supplemental testing. Assuming a prevalence rate of 121.9 per 100,000 for viral markers for HIV, HTLV, HBV, or HCV among prospective donors (Ref. 11), that approximately 80 percent of donations are made by repeat donors [1], that repeat donors average two donated units per year [2], and that first time donors contribute one unit, an estimated 8,887 deferred blood donors and 8,861 plasma donors (including first time and repeat donors) would be identified each year.

FDA assumes that all facilities currently make at least one notification attempt for all deferred donors. However, the percentage of facilities that currently make up to three documented attempts within an 8-week period is not known. FDA has therefore estimated the economic impact for two scenarios in which the cost of compliance is based on the assumption that two additional notification attempts are needed, and these notifications are made via registered mail with a return receipt requested, at a cost of $12.54 [3] per notified donor. Under the first scenario, FDA assumes half of deferred donors are currently notified through a process like the one specified in the proposed rule. In this case, the cost of compliance, based on the cost of up to two additional notifications to the remaining half of the estimated deferred donors totals $55,719 for the blood industry, and an estimated $55,557 for the plasma industry. Under the second scenario, FDA considers that only one-quarter of deferred donors are currently receiving up to three notification attempts. Under this scenario, the cost of up to two additional notifications to the remaining three-quarters of the estimated deferred donors totals $83,578 for the blood industry, and an estimated $83,335 for the plasma industry. Thus, the ongoing notification costs for the blood and plasma industries combined are estimated to range from $111,276 to $166,913 per year.

E. Expected Benefits of the Proposed Rule

As described in the preamble to this rule, notification of donors that they have been deferred and consequently should not attempt subsequent donations will help prevent unsafe units of blood or blood products from entering the blood supply. Notification of donors who are deferred and can self-defer in the future thus adds to the protection provided by donor deferral registries. In FDA's proposed rule on donor testing found elsewhere in this issue of the **Federal Register**, the agency provides an extensive discussion of the benefits of reducing public exposure to the risks of these infectious diseases. FDA refers the reader to this discussion of the significant public health benefits of minimizing patients' risk of being unwittingly exposed to infection with HIV, HTLV, hepatitis B, and hepatitis C.

F. Small Entity Impact

The proposed rule is not expected to have a significant impact on a substantial number of small entities, however, the impact on blood and plasma establishments that qualify as small entities is uncertain. FDA has therefore prepared an initial regulatory flexibility analysis. The blood and plasma establishments affected by the proposed rule are included under the major standard industrial code (SIC) group 80 for providers of health services. According to section 601 of the Regulatory Flexibility Act of 1980, the term ''small entity'' encompasses the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' According to the Small Business Administration (SBA), a small business within the blood industry is an

[1] This percentage is based on American Red Cross estimates based on donations between January 1996 and June 1997.

[2] The estimate of an average of two donations per year for repeat blood donors is based on the Center for Disease Control's (CDC's) analysis of blood donations prepared for HCV lookback.

[3] This estimate is based on two mailings, at a cost of $6.27 each. This cost includes $.32 first class postage plus $4.85 fee for registered mail without insurance, plus $1.10 fee for return receipt requested at the time of mailing showing whom, signature, date and addressee's address (if different) source: USPS 1997 Postal Rates @ ''www.usps.gov/consumer''.

enterprise with less than $5 million in annual receipts. A small organization is a not-for-profit enterprise which is independently owned and operated and is not dominant in its field. A ''small governmental jurisdiction'' generally means governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000.

As noted in the foregoing analysis, the proposed rule is expected to have some cost impact on both plasma and blood collection centers. FDA has registered a total of 487 plasma collection facilities. Of that total, the General Accounting Office (GAO) (Ref. 12) has identified approximately 370 for-profit plasma collection centers that primarily collect paid plasma donations. The remaining 100 or so plasma collection facilities function within blood collection centers with volunteer donors, that are either operated by the American Red Cross, or are independently operated. The vast majority of collected source plasma is processed by four companies: Alpha Therapeutic Corp., Baxter Healthcare Corp., Bayer Corp., and Centeon LLC.

FDA estimates that approximately 90 percent of these 370 paid plasma collection centers are owned by companies that operate a number of centers and have annual receipts in excess of $5 million per year. The remaining 10 percent, or about 37 paid plasma collection centers, may qualify as small business establishments. Of the 100 or so volunteer plasma collection facilities within blood collection centers, the independently operated, not-for-profit blood collection centers would likely qualify as small entities. The potential impact on plasma collection facilities will be a function of the number of donors and the viral marker rates among donors at their facility. The net impact on these facilities, however, is expected to be minor. For example, under cost scenario 1, if the additional yearly cost of $55,557 were evenly distributed across all 487 registered facilities, this would translate to an added cost of $114 per facility per year. Under scenario 2, the added cost per facility would be approximately $171 per year.

The impact on blood collection facilities that qualify as small entities is also uncertain, although it is not expected to be significant. The blood collection facilities that are independent and not-for-profit organizations may qualify as small entities regardless of the size of their operations. The analysis that follows, however, considers the smaller blood collection facilities, because they are expected to experience the greater cost impact. According to the 1996 directory of the AABB, 34 regional and community blood centers have annual revenues of less than $5 million; and each collect no more than 30,000 donations per year. Because of the pre-existing practice of deferred donor notification at these facilities, and the relatively small number of donors that FDA estimates will be deferred based on blood test findings, the impact on these small facilities is expected to be minor. Based on FDA's calculations, facilities with 30,000 donations or less per year would identify about 22 deferred donors per year through blood testing. At a cost of $6.27 per notification via registered mail with a return receipt, if all facilities currently need to make two additional notification attempts under this rule, there would be an average small facility notification cost of $278 (22 x $12.54) per year. Because the estimated one-time cost for the review and revision of current deferral notification SOP's equaled $271 (2/3 x $103 + 1/3 x $616), or about $39 when annualized over a 10-year payment period at a 7-percent interest rate, the average annualized cost impact for the smaller collection centers would be about $317 ($278 + $39), or roughly $0.01 per donation, assuming approximately 30,000 donations per year. It should be noted that blood collection centers that collect both blood and source plasma will not experience a ''double'' impact, because the same donor pool and donations are used for production of the center's blood and plasma products.

The types of professional staff and skills required to perform the required tasks were described in section VI.D of this document. FDA is confident that the tasks specified in the proposed rule can be readily performed by the type of staff already employed at affected blood and plasma establishments.

To alleviate the impact on small entities while continuing to protect public health, the agency is proposing to recommend, but not require, that autologous donors be notified, if they test repeatedly reactive for evidence of infection; FDA also does not require that these donors be deferred. To minimize facility notification efforts while achieving the public health objectives, FDA proposes that notification should not occur until after the results of the approved supplemental testing are available. The proposed regulations are thus expected to help enhance both public health and public confidence in the safety of the blood and plasma supply, while imposing minimum burden on manufacturers.

As an alternative to this proposal, FDA has considered not requiring donor notification of deferral from future donation due to communicable disease testing or failure to satisfy suitability criteria associated with the prevention of communicable disease because it is viewed by many as medical practice. However, the agency has rejected this alternative for the following reason. After a lengthy period of time during which the agency published recommendations to establishments on notifying donors of deferral, inconsistency pertaining to information and counseling provided to the deferred donor has been demonstrated among the establishments. Notification of donor deferral has become a public health issue because donors who are not fully informed of their deferral status due to communicable disease testing or failure to meet suitability criteria associated with the prevention of communicable disease may not take precautions to minimize the transmission of communicable disease to others and may not recognize the importance of not attempting to donate blood or blood components in the future.

VII. The 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 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in this section of this document with an estimate of the annual burden. Included in this estimate is the time for reviewing the 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: General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors.

Description: FDA is proposing requirements for the donor notification process which are intended to prevent further donations from donors who have been deferred for positive test results for evidence of communicable disease agent(s) or for failing to meet the donor suitability criteria intended to reduce the risk of communicable disease agents prior to collection. When a donor is deferred for failing to meet suitability criteria associated with communicable disease agents prior to collection, he or she would be advised not to donate now or in the future and would be provided with information regarding the need for medical followup and counseling. When test results for communicable disease agents are finished, establishment personnel would be required to make at least three attempts to notify donors with positive supplemental (additional, more specific) test results that they are deferred and should have medical followup and counseling. The revisions would require blood and plasma establishments to develop SOP's for deferring donors and for notifying deferred donors and to maintain their permanent address, outline the information that is to be provided to a deferred donor, and to notify deferred donors of positive test results for evidence of infection by communicable disease agent(s) within 8 weeks of the donation initiating deferral, or at their first return visit, whichever is earlier. FDA is proposing these new requirements to help ensure the nation's blood supply is safe by excluding donors who may present significant risks from donating in the future as well as enhancing the public health by assuring that those donors who have been deferred are advised to seek treatment and counseling.

Description of Respondents: Manufacturers of blood, blood components, and blood derivatives.

There are an estimated 2,800 FDA registered blood and Source Plasma collection facilities in the United States that collect approximately 27,000,000 units of Whole Blood and Source Plasma annually. There are approximately 8 million donors of Whole Blood and 1.5 million donors of plasma for a total of 9.5 million donors per year. From such information as is available to FDA, the agency estimates that approximately 1.2 percent of persons who come to donate annually are deferred prior to donating because of disqualifying answers to the medical history and behavior questionnaire. In addition to the 9.5 million donors per year there would be approximately 115,385 potential donors deferred from donating. It is the customary and usual practice of virtually all registered establishments to explain to a donor why he or she is deferred and excluded from donating. Based on such information as is available to FDA, the agency estimates that currently two-thirds of registered establishments voluntarily provide additional information and counseling to a deferred donor. Consequently, only one-third or 933 collection facilities would have additional burden related to this proposed rule. Some industry contacts estimated that it takes on average approximately 5 minutes to provide the deferred donor with the appropriate medical health information. FDA estimates that currently 95 percent of the industry that collects 98 percent of the blood and blood components have voluntarily established SOP's for notifying donors who have repeatedly reactive test results that also are positive by supplemental tests for HIV, HBV, or HCV (the number of donors who test and confirm positive for HTLV is so small that this was not included in the estimate). FDA estimates based on 9.5 million donors annually and the viral marker incidence rates for HIV, HBV, and HCV, that 49,591 donors would be deferred annually due to test results. Consequently, 5 percent (140) of the industry collecting 2 percent (992) of the deferred donors would experience new burden related to this proposed rule. FDA estimates on the average it may take 15 minutes to allow for up to three attempts to contact a donor and request that they return for counseling which may take another 15 minutes for a total of 0.5 hours.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
630.6(a) and (b)[2]	933	41	38,462	.08	3,077
630.6(a), (b), and (c)[3]	140	7	992	0.5	496
TOTAL					4,069

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] Potential donors deferred prior to donation. The number of potential donors deferred annually prior to donation based on failure to meet suitability criteria associated with communicable disease agents is 115,385. Providing information on medical followup and counseling to these deferred donors is estimated to be new burden for approximately one-third of the registered blood and plasma collection facilities.

[3] Donors deferred post donation due to test results. Providing information on medical followup and counseling to donors deferred due to test results may be new burden for approximately 5 percent of the industry collecting from 2 percent of such deferred donors. One hundred and forty represents 5 percent of the 2,800 registered establishments and 992 represents 2 percent of the estimated 49,591 donors deferred annually due to test results.

TABLE 2.— ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
606.100(b)(20)	2,800	1	2,800	2	5,600
606.160(b)(1)(ix)[2]	2,800	59	164,976	3	8,400
606.160(b)(1)(x)[3]	2,800	9,643	27,000,000	0	0
TOTAL					14,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] FDA estimates that annually 115,385 potential donors are deferred prior to donation and 49,591 donors are deferred due to test results. Recording the notification of each deferred donor is estimated to require between 2 and 5 minutes (3 minutes on average).

[3] Recording the donor's permanent address is customary and usual practice in the industry and is not new or additional burden.

In compliance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted a copy of this proposed rule to OMB for review of the information collection provisions. Interested persons are requested to submit written comments regarding information collection by September 20, 1999, to the Office of Information and Regulatory Affairs, OMB (address above), Attention: Desk Officer for FDA.

VIII. Environmental Impact

The agency has determined under 21 CFR 25.31(j) that this action is of a type that not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Request for Comments and Effective Date

Interested persons may, on or before November 17, 1999, submit to the Docket Management Branch (address above) written comments regarding this proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA is proposing that any final rule that may issue based upon this proposed rule become effective 180 days after its date of publication in the **Federal Register**.

X. 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. *Morbidity and Mortality Weekly Report*, vol. 32, pp. 101–103, March 4, 1983.

2. *Morbidity and Mortality Weekly Report*, vol. 34, pp. 1–5, January 11, 1985.

3. *Morbidity and Mortality Weekly Report*, vol. 36, pp. 509–515, August 14, 1987.

4. *Morbidity and Mortality Weekly Report*, vol. 36, pp. 833–840, January 8, 1988.

5. *Morbidity and Mortality Weekly Report*, vol. 38 (No. S–7), July 21, 1989.

6. *Morbidity and Mortality Weekly Report*, vol. 41 (No. RR–2), pp. 1–9, February 28, 1992.

7. *Morbidity and Mortality Weekly Report*, vol. 37, pp. 736–747, December 9, 1988.

8. *Morbidity and Mortality Weekly Report*, vol. 40 (No. RR–4), pp. 1–17, April 19, 1991.

9. Wallace, E. L., W. H. Churchill, D. M. Surgenor, J. An, G. Cho, S. McGurk, and L. Murphy, ''Collection and Transfusion of Blood and Blood Components in the United States, 1992,'' *Transfusion*, 1995; vol. 35, No. 10, pp. 802–812.

10. General Accounting Office, ''Blood Safety: Enhancing Safeguards Would Strengthen the Nation's Blood Supply,'' GAO–HEHS–97–143, June 1997.

11. Glynn, S. A., G. B. Schreiber, M. P. Busch, S. H. Kleinman, A. E. Williams, C. C. Nass, H. E. Ownby, and J. W. Smith, for the Retrovirus Epidemiology Donor Study, ''Demographic Characteristics, Unreported Risk Behaviors, and the Prevalence and Incidence of Viral Infections: A Comparison of Apheresis and Whole-Blood Donors,'' *Transfusion*, April 1998, vol. 38, pp. 350–358.

12. General Accounting Office, ''Blood Plasma Safety: Plasma Product Risks Are Low if Good Manufacturing Practices Are Followed,'' GAO–HEHS–98–205, September 1998.

Lists of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 630

Biologics, Blood, Reporting and recordkeeping requirements.

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 Chapter I be amended as follows:

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

1. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371,374; 42 U.S.C. 216, 262, 263a, 264.

2. Section 606.100 is amended by adding paragraph (b)(20) to read as follows:

§ 606.100 Standard operating procedures.

* * * * *

(b) * * *

(20) Procedures for donor deferral as prescribed in § 610.41 of this chapter and donor notification, including procedures for the appropriate followup if the initial attempt at notification fails, as prescribed in § 630.6 of this chapter.

* * * * *

3. Section 606.160 is amended by adding paragraphs (b)(1)(ix) and (b)(1)(x) to read as follows:

§ 606.160 Records.

* * * * *

(b) * * *

(1) * * *

(ix) Notification of deferred donors, including appropriate followup if the initial attempt at notification fails.

(x) To facilitate the notification of deferred donor, the donor's permanent address.

* * * * *

4. Part 630 is added to read as follows:

PART 630—GENERAL REQUIREMENTS FOR BLOOD, BLOOD COMPONENTS, AND BLOOD DERIVATIVES

Sec.
630.6 Donor notification.

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371; 42 U.S.C. 216, 262, 263.

§ 630.6 Donor notification.

(a) An establishment that collects blood or blood components shall notify donors who have been deferred based on results of tests for evidence of infection with a communicable disease agent as required by § 610.41 of this chapter or based on deferral for suitability criteria. Blood establishments shall attempt to obtain the results of supplemental testing required under § 610.40(c) of this chapter prior to notifying donors of their deferral. If notification occurs prior to receipt of such results, blood establishments shall renotify donors of the results of the supplemental testing. Blood establishments shall notify donors as described in paragraph (b) of this section.

(b) The notification shall provide the following information to a donor who has been deferred from donating as described in paragraph (a) of this section:

(1) That the donor has been deferred and the reason for deferral;

(2) The types of donations of blood or blood components which the donor should not donate in the future;

(3) Where applicable, the results of tests for evidence of infection due to communicable disease agent(s), that were a basis for deferral under § 610.41 of this chapter, including results of supplemental (i.e. additional, more specific) tests as required in § 610.40(c) of this chapter;

(4) Information concerning appropriate medical followup and counseling; and

(5) Where applicable, the possibility that the donor may be found suitable for future donations.

(c) The notification process shall include a minimum of three attempts to

notify the donor and be completed within 8 weeks after the determination that the donor should be deferred or at the first return visit of the deferred donor after the determination is made, whichever is earlier.

Dated: April 20, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 99–21295 Filed 8–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606 and 640

[Docket No. 98N–0673]

Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, and Source Plasma to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. FDA is issuing these amendments directly as a final rule because they are noncontroversial and there is little likelihood that FDA will receive any significant comments opposing the rule. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule under FDA's usual procedures for notice and comment in the event the agency receives any significant adverse comments. If FDA receives any significant adverse comment sufficient to terminate the direct final rule, FDA will consider such comments on the proposed rule in developing the final rule. FDA is issuing this rule as part of the agency's ''Blood Initiative'' in which FDA is reviewing and revising, when appropriate, its regulations, policies, guidance, and procedures related to blood, blood components, and Source Plasma.

DATES: This rule is effective February 11, 2000. Submit written comments on or before December 3, 1999. If no timely significant comments are received, the agency will publish a document in the **Federal Register** within 30 days after the comment period on this direct final rule ends, confirming the effective date of the final rule. If timely significant adverse comments are received, the agency will publish a document in the **Federal Register** withdrawing the direct final rule before its effective date.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Dano B. Murphy, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Blood Initiative

For a variety of reasons, FDA has decided to comprehensively review and, as necessary, revise its regulations, policies, guidance and procedures related to the licensing and regulation of blood products. In the **Federal Register** of June 3, 1994 (59 FR 28821 and 59 FR 28822, respectively), FDA issued two documents entitled ''Review of General Biologics and Licensing Regulations'' (Docket No. 94N–0066) and ''Review of Regulations for Blood Establishments and Blood Products'' (Docket No. 94N–0080). The documents announced the agency's intent to review biologics regulations, 21 CFR parts 600, 601, 606, 607, 640, and 660 and requested written comments from the public. Interested persons were given until August 17, 1994, to respond to the documents. In response to requests for additional time, FDA twice extended the comment period, as announced in the **Federal Register** of August 17, 1994 (59 FR 42193), and November 14, 1995 (59 FR 56448). In addition, FDA responded to requests for a public meeting to allow for the presentation of comments regarding the agency's intent to review the biologics regulations. On January 26, 1995, FDA held a public meeting to provide an opportunity for all interested individuals to present their comments and to assist the agency in determining whether the regulations should be revised, rescinded, or continued without change. Since the time of the regulation review, FDA has implemented a number of changes to its regulations and policies applicable to the general biologics and licensing regulations, some of which applied to blood products as well as other biological products. (See, e.g., the final rules issued on May 14, 1996 (61 FR 24313); August 1, 1996 (61 FR 40153); November 6, 1996 (61 FR 57328); July 24, 1997 (62 FR 39890); and October 15, 1997 (62 FR 53536).)

Because of the importance of a safe national blood supply, the U.S. House of Representatives Committee on Government Reform and Oversight, Subcommittee on Human Resources and Intergovernmental Relations (the Subcommittee) and other groups such as the General Accounting Office (GAO), and the Institute of Medicine (IOM) have reviewed the agency's polices, practices, and regulations. Reports issued following the respective reviews contained a number of recommendations as to how FDA might improve the biologics regulations, particularly as they apply to the continued safety of blood products. The relevant reports are: (1) ''Protecting the Nation's Blood Supply From Infectious Agents: The Need for New Standards to Meet New Threats,'' by the Subcommittee (August 2, 1996); (2) ''Blood Supply: FDA Oversight and Remaining Issues of Safety,'' by GAO (February 25, 1997); (3) ''Blood Supply: Transfusion-Associated Risks,'' by GAO (February 25, 1997); and (4) ''HIV and the Blood Supply: An Analysis of Crisis Decisionmaking,'' by IOM (July 13, 1995). These reports are on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this document.

FDA has reviewed these reports and agrees with the majority of the recommendations contained within them. However, rather than to only respond specifically to the recommendations from the Subcommittee, GAO, IOM, and the public, FDA has convened a number of internal task forces to review a variety of issues related to the regulation of blood and blood products, including how to most appropriately update the existing regulations applicable to blood and blood products. In the future, FDA intends to issue a number of blood-related regulations that various FDA task groups are preparing. FDA emphasizes that for many of the changes discussed in section III of this document, additional issues related to the regulations now being amended continue to be under consideration by the agency. Further, more substantive changes may be proposed at a later date. Accordingly, any comment recommending an additional change to these regulations will not be considered to be an ''adverse comment'' unless the comment demonstrates that the change being made in the direct final rule represents a major departure from current regulations or accepted industry standards, or cannot be implemented without additional amendments to the regulations.

FDA is not describing the specific recommendations it received and the numerous objectives of the Blood Initiative in this document. Future rulemaking and other notices will describe and discuss specific recommendations and regulatory objectives as they apply to each rulemaking.

II. Legal Authority

FDA is issuing this new rule under the biologics products and

communicable disease provisions of the Public Health Service Act (the PHS Act) (42 U.S.C. 262–264) and the drug, device, and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 331, 351–353, 355, 360, 360j, 371, and 374). Under these provisions of the PHS Act and the act, FDA has the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, potent, and properly labeled and to prevent the introduction, transmission, and spread of communicable disease.

III. Highlights of the Direct Final Rule

FDA is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, and Source Plasma to be more consistent with current practices and to remove unnecessary or outdated requirements. FDA is issuing these amendments as a direct final rule because the agency has concluded they are noncontroversial and that there is little likelihood that there will be comments opposing the rule. FDA emphasizes that for many of the following changes, additional issues related to the regulations now being amended continue to be under consideration by the agency. Further, more substantive changes may be proposed at a later date. Accordingly, any comment recommending additional changes to these regulations will not be considered to be an ''adverse comment'' unless the comment demonstrates that the change being made in the direct final rule represents a major departure from current regulations or accepted industry standards, or cannot be implemented without additional amendments to the regulation. In the following paragraphs, FDA discusses each of the rule changes in the direct final rule.

Part 606 (21 CFR part 606) is amended as follows:

Section 606.3, Definitions, is amended so that the definitions provided in the section are consistent with current meanings and usages.

The definition of ''Component'' in § 606.3(c) is amended to apply to blood obtained from a single donor and no longer includes the wording ''single-donor unit.'' This change is to clarify that blood components may be collected by means other than separation from a unit of whole blood, such as by automated plasmapheresis.

The definition of ''Plasmapheresis'' in § 606.3(e) is amended by removing the restriction that plasmapheresis may be ''immediately repeated, once'' because current automated plasmapheresis collection practices often use more than two cycles for collection.

The definition of ''Plateletpheresis'' in § 606.3(f) is amended to provide for the common practice of collecting plasma as a by-product of a plateletpheresis procedure in lieu of returning all of the residual plasma to the donor.

The definition of ''Compatibility testing'' in § 606.3(j) is amended by removing the reference to serological tests and making the definition more general to apply to all tests performed to establish the matching of a donor's blood or blood components with that of a potential recipient. This change will provide for current practices used in compatibility testing, such as the electronic crossmatch and the immediate spin crossmatch.

Section 606.100(b) and (d) are amended to reflect changes in terminology, requirements for testing, and availability of standard operating procedures (SOP's) to be consistent with current practices. Section 606.100(b) is also amended by removing the references to homologous and autologous transfusion because subpart F of part 606, applies to all blood products intended for transfusion. In addition, the phrase ''unless this is impractical'' is removed because it is current good manufacturing practice (CGMP) to make the applicable SOP's available in all areas where procedures are performed. Section 606.100(b)(7) is amended by removing ''including testing for hepatitis B surface antigen as prescribed in § 610.40 of this chapter'' because other tests, in addition to tests for hepatitis B surface antigen, are now required and specific reference to this test is unnecessary. Section 606.100(b)(18) is amended by removing the bracketed term ''salvaged'' because its use in § 606.100 is inconsistent with the use of ''salvaged plasma'' in § 640.76. Section 606.100(d) is amended by removing references to specific organizations because any SOP's meeting FDA requirements would be acceptable, regardless of their source, and because FDA cannot assure that SOP's adopted by particular organizations remain in compliance with FDA's regulatory requirements.

Section 606.121(a) is amended by removing the reference that the ''Guideline for the Uniform Labeling of Blood and Blood Components'' is available from Dockets Management Branch as this is no longer the appropriate office from which to request this document and by removing the reference to the American Blood Commission because the organization no longer exists.

Section 606.121(d)(2) specifies the color requirements for printing the container label and is amended by adding ''or in solid black'' because some blood centers use on-demand printers for printing labels, that do not have the capability to print in multiple colors.

Section 606.121(e)(1)(ii) prescribes the specific anticoagulants that shall be identified on the container label. Section 606.121(e)(1)(ii) is amended by deleting the references to the names of specific anticoagulants. This change will allow for more flexibility for the acceptance and use of new anticoagulants or changes in nomenclature of existing anticoagulants without requiring amendments to the regulations.

Section 606.122(f) specifies the warning statement required in the instruction circular and is amended by removing the reference to ''hepatitis'' and adding ''infectious agents'' to include a reference to the additional infectious disease marker tests routinely performed on blood and blood components because the product intended for transfusion carries the risk of transmitting other infectious agents.

Section 606.122(n)(4) specifies that the instruction circular for cryoprecipitated AHF shall contain instructions to thaw the product at a temperature of 37 °C and is amended to allow instructions for thawing between 30 and 37 °C, permitting more flexibility in the preparation of the component.

Section 606.151(b) is amended, consistent with current accepted practices, to permit SOP's to include use of recipient serum samples less than 3-days old for compatibility testing if the recipient has been pregnant or transfused within the preceding 3 months.

Section 606.151(c) describes compatibility testing and is amended by changing ''the testing of the donor's cells with the recipient's serum'' to ''the testing of the donor's cell type with the recipient's serum type'' and by replacing ''agglutinating, coating, and hemolytic antibodies, which shall include the antiglobulin method'' with ''incompatibility.'' This change is intended to accommodate the use of such procedures as an immediate spin crossmatch and an electronic crossmatch.

Section 606.151(e) is amended by changing ''by the physician requesting the procedure.'' to ''by a physician.'' to take into account that a patient may have more than one physician in attendance at any time.

Section 606.160(b)(2)(v) is amended by changing ''person(s) responsible'' to ''the person(s) performing the

procedure'' to clarify that the person(s) performing the labeling procedure is responsible for documenting the performance of that procedure.

Section 606.170(b) is amended by deleting ''telegraph'' and adding ''facsimile, express mail, or electronically transmitted mail'' to the possible methods by which the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, shall be notified of a complication of blood collection or transfusion resulting in a fatality.

Part 640 (21 CFR part 640) is amended as follows:

Section 640.2(b) is removed because Whole Blood collection in open systems is no longer acceptable nor has it been performed for many years. Section 640.2(d) is revised. In § 640.2 paragraphs (c), (e), and (f) are redesignated as paragraphs (b), (c), and (d), respectively. Redesignated § 640.2(b) and (c)(2) are revised by removing references to the original blood container because, consistent with current accepted practices such as washing, freezing, deglycerolization, and division of units using sterile connecting devices, the original blood container may, in many cases, no longer be the final container.

Section 640.3(b) is amended by adding a reference to autologous donations to permit the collection of autologous Whole Blood at intervals of less than 8 weeks, consistent with the current practice of shorter time intervals between collections of blood and blood components from donors participating in autologous collection programs. Section 640.3(b)(3) is amended to provide hematocrit and hemoglobin values to be used when determining whether a potential donor can donate Whole Blood, by adding to the end of the current paragraph ''or a hematocrit value of 38 percent, and for autologous donations, a blood hemoglobin level which shall be demonstrated to be no less than 11.0 g of hemoglobin per 100 mL of blood or a hematocrit value of 33 percent.'' The acceptable hemoglobin and hematocrit values for autologous donors are consistent with current industry practice and the American Association of Blood Banks technical manual, 12th edition.

Sections 640.3(c)(1) and 640.63(c)(11) are amended by inserting ''after the age of eleven'' after the term ''hepatitis'' because establishments may collect Whole Blood from donors who have a history of hepatitis prior to age eleven to be consistent with recommendations in the FDA memorandum dated April 23, 1992, entitled ''Exemptions to Permit Persons with a History of Viral Hepatitis Before the Age of Eleven to serve as Donors of Whole Blood and Plasma: Alternative Procedure''(21 CFR 640.120). Additional issues concerning donors who have a history of viral hepatitis continued to be reviewed by the agency and may be addressed in future rulemaking objectives.

Sections 640.3(c)(2) and 640.63(c)(12) are amended by changing the deferral period for donors of Whole Blood who have had close contact with an individual having viral hepatitis from ''six months'' to ''12 months.'' Similarly, §§ 640.3(c)(3) and 640.63(c)(13) are amended by changing the deferral period from ''six months'' to ''12 months'' for donors of Whole Blood who received human blood, or any derivative of human blood which FDA has identified as a possible source of viral hepatitis. These changes are consistent with recommendations made in the FDA memoranda dated April 23, 1992, entitled ''Revised Recommendations for the Prevention of Human Immunodeficiency Virus Transmission by Blood and Blood Products and Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV).'' In addition, §§ 640.3(c)(3) and 640.63(c)(13) have been amended by changing the reference from a ''licensed establishment'' to a ''blood establishment'' to clarify that the regulation applies to all establishments engaged in the collection of blood and blood products.

Sections 640.3(e), 640.31(c), and 640.51(c) are removed because FDA has concluded that it is no longer necessary to defer donors participating in red blood cell immunization programs. Previously, donors participating in red blood cell immunization programs were deferred for 12 months because fresh red blood cells were used to immunize donors. Red blood cells now used in immunization programs are carefully screened and quarantined thereby minimizing the risk of transmitting infectious agents. See FDA memorandum dated March 14, 1995, entitled ''Revised Recommendations for Red Blood Cell Immunization Programs for Source Plasma Donors'' for additional information about current red blood cell immunization practices.

Section 640.4(b) is amended by removing the word ''clinic'' and replacing it with the word ''center'' to reflect current terminology and by changing the word ''licensed'' to ''blood'' to clarify that the regulation applies to all blood establishments engaged in the collection of blood and blood products. Section 640.4(d) is amended by removing the reference to the specific anticoagulant formulae. Section 640.4(d)(1) through (d)(4) is removed because FDA has determined it is unnecessary to provide specific formulae for anticoagulant solutions in the regulations and that manufacturers should be able to use any anticoagulant approved by FDA for such use. Sections 640.13(a), 640.22(a), 640.32(a), and 640.52(a) are amended to remove references to § 640.4(d)(2) and (h), which are being removed.

Section 640.4(g)(5) has been changed to include the use of different anticoagulants in segments for compatibility testing to be consistent with the use of different approved anticoagulants in the manufacture of blood and blood products. Section 640.4(h) is removed because heparin anticoagulant solutions are no longer used for the routine collection of blood.

Section 640.5(c) is amended to be consistent with current Rh factor testing practices by removing ''and for other Rh-Hr factors,'' because these tests are not routinely performed. The section is also changed to specify that blood testing negative using Anti-D Blood Grouping Reagents may only be labeled ''Rh Negative'' if the confirmatory testing includes tests for weak expressions of D. These changes have been made to be consistent with current accepted practices which designate that tests for weak expressions of D be performed and the product labeled consistent with the results of those tests.

Sections 640.6(c) and 640.15(c) are removed because the use of more modern methods of manufacturing and equipment have eliminated the use of pilot tubes attached to blood units. In § 640.15 paragraph (d) is redesignated as paragraph (c).

Section 640.16(a) is amended by inserting ''or additive solution'' after ''cryoprotective substance'' to reflect an additional procedure for prolonging shelf life now in use in which all the plasma is removed from a unit of blood.

Section 640.16(b) is amended by removing all but the first sentence. The removed text describes blood collection procedures to be followed when using open vented systems. Use of open vented systems is no longer consistent with CGMP and has not been used for many years.

All references to ''pilot tubes'' and ''pilot samples'' have been replaced with the words ''sample(s)'' or ''segment(s)'' to reflect current terminology for various testing specimens. The following sections are amended by replacing ''pilot tubes,''

''pilot samples,'' or ''pilot sample tubes'' with ''segments'' or ''samples'' as appropriate: §§ 640.2(e)(2), 640.4(g) introductory text, and paragraphs (g)(1), (g)(2), (g)(4), and (g)(5), 640.5, 640.15(a) through (c), and 640.69(d) introductory text, and paragraphs (d)(1) through (d)(4).

Section 640.23(a) is amended to include the preparation of Platelets prepared by automated collection procedures and to allow the group and typing tests performed on Platelets prepared by apheresis to be valid for a period not to exceed 3 months, thereby, eliminating the necessity of repeat testing of blood samples from donors participating in frequent plateletpheresis collection procedures.

Section 640.24(b) is amended by changing the time period for separation of the platelet concentrate from ''4 hours'' to ''within the time period specified in the directions for use for the specific device.'' Similar changes are made to the timeframe for the storage of plasma that is set forth in § 640.34(a) through (d) and (e)(1) and the freezing of plasma set forth in § 640.54(a)(2). These changes, consistent with current accepted practices, permit more flexibility by permitting different timeframes depending on the particular blood collection device being used.

Sections 640.25(b) and 640.56(a) are amended to require testing only in those months in which blood products are prepared for use. This eliminates the need for performing quality control procedures during those months when product is not being manufactured.

Sections 640.25(c), 640.56(c), and 640.71(a) are amended to update references to cite the ''Clinical Laboratories Improvement Amendments of 1988 (CLIA)'' consistent with nomenclature in the regulations implementing CLIA in 42 CFR part 493.

Section 640.34(d) is amended by deleting the reference to storing platelet rich plasma at temperatures between 1 and 6 °C because storage at such temperatures adversely affects platelet function.

Section 640.34(e)(2) and (e)(3) are amended to include the proper name of the product ''Plasma, Cryoprecipitate Reduced'' as per recommendations of the Blood Products Advisory Committee at its September 18 and 19, 1997 meeting. Section 640.34(g)(2) is amended to permit proof of continuous monitoring of the temperature to be within acceptable ranges for the product as an alternative to requiring the storing of the product in a manner to show evidence of thawing. FDA believes that, with current technology, monitoring systems of freezers used for storage are adequately sensitive and reliable to detect any significant rise in storage temperature.

Section 640.62 requiring that a qualified licensed physician be on the premises when donor suitability is being determined is amended to require a qualified licensed physician to be physically available on the premises, or be available to attend to the donor within 15 minutes, when a pheresis procedure is being performed, for consultation and management of donor adverse reactions, except that the qualified licensed physician shall be physically available on the premises when red blood cell immunizations are being performed. FDA has determined that a qualified licensed physician must always be readily available, if needed, and shall be on the premises for red blood cell immunizations.

Section 640.63(c)(3) is amended by adding at the end of the sentence ''or a hematocrit level of 38 percent,'' which is equivalent to a hemoglobin level of 12.5 g per 100 mL of blood, to be consistent with current accepted practices.

Section 640.63(c)(5) is amended by adding ''or total plasma'' after ''A total serum'' to be consistent with current accepted practice of using a capillary tube coated with anticoagulant for fingerstick sample collection.

Section 640.65(b)(4) is amended by changing ''in any 48-hour period'' to ''2-day'' to permit more flexibility in scheduling donor appointments and by adding the word ''manual'' to the phrases ''during a plasmapheresis procedure'' to clarify that the regulation applies to a manual plasmapheresis collection procedure, but does not apply to automated apheresis.

Section 640.65(b)(5) is amended by adding ''during a manual plasmapheresis procedure'' after the phrases ''removed from the donor'' to clarify that the regulation applies to a manual plasmapheresis collection procedure, but does not apply to automated apheresis..

Section 640.65(b)(8) is added to address the collection of Source Plasma using automated collection devices. The regulation delineates the frequency of collection consistent with § 640.65(b)(4) and (b)(5) and the volume of plasma to be collected during such procedures consistent with the plasma collection volumes approved for each device and with recommendations included in the FDA memorandum to all plasma establishments dated November 4, 1992, entitled ''Volume Limits for Automated Collection of Source Plasma.''

Section 640.72(a)(1) is amended by replacing ''compiled every 3 months'' with ''shall be available'' to eliminate the necessity of compiling documents at specified time intervals.

IV. Rulemaking Action

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described its procedures on when and how FDA will employ direct final rulemaking. FDA has determined that this rule is appropriate for direct final rulemaking because FDA views this rule as including only noncontroversial amendments and anticipates no significant adverse comments. Consistent with FDA's procedures on direct final rulemaking, FDA is publishing elsewhere in this issue of the **Federal Register**, a companion proposed rule to amend the biologics regulations by removing, revising, and updating existing regulations to be more consistent with current accepted practices. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for the direct final rule runs concurrently with the companion proposed rule. Any comment received under the companion proposed rule will be considered as comments regarding the direct final rule.

FDA has provided a comment period on the direct final rule of 75 days after August 19, 1999. If the agency receives any significant adverse comment, FDA intends to withdraw this direct final rule action by publication of a document in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a rule change in addition to the rule would not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and

that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not subjects of a significant adverse comment.

If any significant adverse comment is received during the comment period, FDA will publish, within 30 days after the comment period ends, a document withdrawing the direct final rule. If FDA withdraws the direct final rule, any comments received will be applied to the proposed rule and will be considered in developing a final rule using the usual Administrative Procedure Act notice-and-comment procedures.

If FDA receives no significant adverse comments during the specified comment period, FDA intends to publish a confirmation document within 30 days after the comment period ends confirming the effective date.

V. Analysis of Impacts

A. Review Under Executive Order 12866 and the Regulatory Flexibility Act and Unfunded Mandates Reform Act of 1995

FDA has examined the impact of the direct final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U. S. C. 601–612), and the Unfunded Mandates Reform Act of 1995 (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 impact; and equity). The agency believes that this direct final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. This direct final rule is not a significant regulatory action as defined by the Executive Order and therefore is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options to minimize any significant impact of a rule on small business entities. Because the direct final rule amendments have no compliance costs and do not result in any new requirements, the agency certifies that the direct final rule will not have a significant negative economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required. This direct final rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, and tribal governments in the aggregate, or by the private sector in any 1 year.

B. Environmental Impact

The agency has determined under 21 CFR 25.31(j) 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.

VI. The Paperwork Reduction Act of 1995

This direct final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Request for Comments

Interested persons may, on or before December 3, 1999, submit to the Docket Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and authority delegated by the Commissioner of Food and Drugs, 21 CFR parts 606 and 640 are amended as follows:

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

1. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

2. Section 606.3 is amended by revising paragraphs (c), (e), (f), and (j) to read as follows:

§ 606.3 Definitions.

* * * * *

(c) *Component* means that part of a single-donor's blood separated by physical or mechanical means.

* * * * *

(e) *Plasmapheresis* means the procedure in which blood is removed from the donor, the plasma is separated from the formed elements and at least the red blood cells are returned to the donor.

(f) *Plateletpheresis* means the procedure in which blood is removed from a donor, a platelet concentrate is separated, and the remaining formed elements are returned to the donor along with a portion of the residual plasma.

* * * * *

(j) *Compatibility testing* means the tests performed to establish the matching of a donor's blood or blood components with that of a potential recipient.

3. Section 606.100 is amended by revising the introductory text of paragraphs (b) and (d), and by revising paragraphs (b)(7) and (b)(18) to read as follows:

§ 606.100 Standard operating procedures.

* * * * *

(b) Written standard operating procedures shall be maintained and shall include all steps to be followed in the collection, processing, compatibility testing, storage, and distribution of blood and blood components for transfusion and further manufacturing purposes. Such procedures shall be available to the personnel for use in the areas where the procedures are performed. The written standard operating procedures shall include, but are not limited to, descriptions of the following, when applicable:

* * * * *

(7) All tests and repeat tests performed on blood and blood components during manufacturing.

* * * * *

(18) Procedures for preparing recovered plasma, if performed, including details of separation, pooling, labeling, storage, and distribution.

* * * * *

(d) In addition to the requirements of this subpart and in conformity with this section, any facility may utilize current standard operating procedures such as the manuals of the organizations, as long as such specific procedures are consistent with, and at least as stringent as, the requirements contained in this part.

* * * * *

4. Section 606.121 is amended by revising paragraphs (a), (d)(2), and (e)(1)(ii) to read as follows:

§ 606.121 Container label.

(a) The container label requirements are designed to facilitate the use of a uniform container label for blood and blood components (except Source Plasma) by all blood establishments.

* * * * *

(d) * * *

(2) The proper name of the product, any appropriate modifier(s), the donor classification statement, and the statement ''properly identify intended recipient'' shall be printed in solid red or in solid black.

* * * * *

(e) * * *

(1) * * *

(ii) The name of the applicable anticoagulant immediately preceding and of no less prominence than the proper name approved for use by the Director, Center for Biologics Evaluation and Research.

* * * * *

5. Section 606.122 is amended by revising paragraphs (f) and (n)(4) to read as follows:

§ 606.122 Instruction circular.

* * * * *

(f) The statements: ''Warning. The risk of transmitting infectious agents is present. Careful donor selection and available laboratory tests do not eliminate the hazard.''

* * * * *

(n) * * *

(4) Instructions to thaw the product for no more than 15 minutes at a temperature between 30 and 37 °C.

* * * * *

6. Section 606.151 is amended by revising paragraphs (b), (c), and (e) to read as follows:

§ 606.151 Compatibility testing.

* * * * *

(b) The use of fresh recipient serum samples less than 3-days old for all pretransfusion testing if the recipient has been pregnant or transfused within the previous 3 months.

(c) The testing of the donor's cell type with the recipient's serum type by a method that will demonstrate incompatibility.

* * * * *

(e) Procedures to expedite transfusion in life-threatening emergencies. Records of all such incidents shall be maintained, including complete documentation justifying the emergency action, which shall be signed by a physician.

7. Section 606.160 is amended by revising paragraph (b)(2)(v) to read as follows:

§ 606.160 Records.

* * * * *

(b) * * *

(2) * * *

(v) Labeling, including initials of the person(s) performing the procedure.

* * * * *

8. Section 606.170 is amended by revising paragraph (b) to read as follows:

§ 606.170 Adverse reaction file.

* * * * *

(b) When a complication of blood collection or transfusion is confirmed to be fatal, the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, shall be notified by telephone, facsimile, express mail, or electronically transmitted mail as soon as possible; a written report of the investigation shall be submitted to the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, within 7 days after the fatality by the collecting facility in the event of a donor reaction, or by the facility that performed the compatibility tests in the event of a transfusion reaction.

(Information collection requirements approved by the Office of Management and Budget under control number 0910–0116)

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

9. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

10. Section 640.2 is amended by removing paragraphs (b) and (d), by redesignating paragraphs (c), (e), and (f) as paragraphs (b), (c), and (d), respectively, and by revising newly redesignated paragraphs (b) and (c)(2) to read as follows:

§ 640.2 General requirements.

* * * * *

(b) *Blood container.* The blood container shall not be entered prior to issue for any purpose except for blood collection. Such container shall be uncolored and transparent to permit visual inspection of the contents and any closure shall be such as will maintain an hermetic seal and prevent contamination of the contents. The container material shall not interact with the contents under the customary conditions of storage and use, in such a manner as to have an adverse effect upon the safety, purity, or potency of the blood.

(c) * * *

(2) A segment is properly attached and has not been removed, except that blood lacking a properly attached segment may be reissued in an emergency provided it is accompanied by instructions for sampling and for use within 6 hours after entering the container for sampling;

* * * * *

11. Section 640.3 is amended by revising the introductory text of paragraph (b), by revising paragraphs (b)(3), (c)(1), (c)(2), and (c)(3) and by removing and reserving paragraph (e) to read as follows:

§ 640.3 Suitability of donor.

* * * * *

(b) *Qualifications of donor; general.* Except as provided in paragraph (f) of this section and for autologous donations, a person may not serve as a source of Whole Blood more than once in 8 weeks. In addition, donors shall be in good health, as indicated in part by:

* * * * *

(3) For allogeneic donors, a blood hemoglobin level which shall be demonstrated to be no less than 12.5 grams (g) of hemoglobin per 100 milliliters (mL) of blood; or a hematocrit value of 38 percent, and for autologous donors, a blood hemoglobin level which shall be demonstrated to be no less than 11.0 g of hemoglobin per 100 mL of blood or a hematocrit value of 33 percent.

* * * * *

(c) * * *

(1) A history of viral hepatitis after the age of eleven;

(2) A history of close contact within 12 months of donation with an individual having viral hepatitis;

(3) A history of having received within 12 months of donation, human blood or any derivative of human blood which the Food and Drug Administration has advised the blood establishment is a possible source of viral hepatitis.

* * * * *

12. Section 640.4 is amended by removing paragraphs (d)(1) through (d)(4) and (h), by redesignating paragraph (i) as paragraph (h), and revising paragraphs (b) and (d), the introductory text of paragraph (g), and paragraphs (g)(1), (g)(2), (g)(4), and (g)(5) to read as follows:

§ 640.4 Collection of the blood.

* * * * *

(b) *The donor center.* The pertinent requirements of §§ 600.10 and 600.11 of this chapter shall apply at both the

blood establishment and at any other place where the bleeding is performed.

* * * * *

(d) *The anticoagulant solution*. The anticoagulant solution shall be sterile and pyrogen-free. Anticoagulant solutions shall be compounded and used according to a formula approved by the Director, Center for Biologics Evaluation and Research.

* * * * *

(g) *Samples for laboratory tests*. Samples for laboratory tests shall meet the following standards:

(1) One or more segments shall be provided with each unit of blood when issued or reissued except as provided in § 640.2(e)(2) and all segments shall be from the donor who is the source of the unit of blood.

(2) All samples for laboratory tests performed by the manufacturer and all segments accompanying a unit of blood shall be collected at the time of filling the original blood container.

* * * * *

(4) All segments accompanying a unit of blood shall be attached to the whole blood container before blood collection, in a tamper proof manner that will conspicuously indicate removal and reattachment.

(5) Segments for compatibility testing shall contain blood mixed with the appropriate anticoagulant.

* * * * *

13. Section 640.5 is amended by revising the introductory text and paragraph (c) to read as follows:

§ 640.5 Testing the blood.

All laboratory tests shall be made on a specimen of blood taken from the donor at the time of collecting the unit of blood, and these tests shall include the following:

* * * * *

(c) *Determination of the Rh factors*. Each container of Whole Blood shall be classified as to Rh type on the basis of tests done on the sample. The label shall indicate the extent of typing and the results of all tests performed. If the test, using Anti-D Blood Grouping Reagent, is positive, the container may be labeled ''Rh Positive''. If this test is negative, the results shall be confirmed by further testing which shall include tests for the Rh_o variant (D^u). Blood may be labeled ''Rh Negative'' if further testing is negative. Units testing positive after additional more specific testing shall be labeled as ''Rh Positive.'' Only Anti-Rh Blood Grouping Reagents licensed under, or that otherwise meet the requirements of, the regulations of this subchapter shall be used, and the technique used shall be that for which the reagent is specifically designed to be effective.

* * * * *

§ 640.6 [Amended]

14. Section 640.6 *Modifications of Whole Blood* is amended by removing paragraph (c).

15. Section 640.13 is amended by revising paragraph (a) to read as follows:

§ 640.13 Collection of the blood.

(a) The source blood shall be collected as prescribed in § 640.4.

* * * * *

16. Section 640.15 is revised to read as follows:

§ 640.15 Samples for testing.

Samples collected in integral tubing shall meet the following standards:

(a) One or more segments of either the original blood or of the Red Blood Cells being processed shall be provided with each unit of Red Blood Cells when issued or reissued.

(b) Before they are filled, all segments shall be marked or identified so as to relate them to the donor of that unit of red cells.

(c) All segments accompanying a unit of Red Blood Cells shall be filled at the time the blood is collected or at the time the final product is prepared.

17. Section 640.16 is amended by revising paragraphs (a) and (b) to read as follows:

§ 640.16 Processing.

(a) *Separation*. Within the timeframe specified in the directions for the use of the specific devices, Red Blood Cells may be prepared either by centrifugation, done in a manner that will not tend to increase the temperature of the blood, or by normal undisturbed sedimentation. A portion of the plasma sufficient to insure optimal cell preservation shall be left with the red cells except when a cryoprotective substance or additive solution is added for prolonged storage.

(b) *Sterile system*. All surfaces that come in contact with the red cells shall be sterile and pyrogen-free.

* * * * *

18. Section 640.22 is amended by revising paragraph (a) to read as follows:

§ 640.22 Collection of source material.

(a) Whole blood used as the source of Platelets shall be collected as prescribed in § 640.4.

* * * * *

19. Section 640.23 is amended by revising paragraph (a) to read as follows:

§ 640.23 Testing the blood.

(a) Blood from which plasma is separated for the preparation of Platelets or Platelets, Pheresis shall be tested as prescribed in §§ 610.40 and 610.45 of this chapter and § 640.5(a), (b), and (c). Results of tests performed in accordance with § 640.5(b) and (c) for Platelets, Pheresis products shall be valid for a period not to exceed 3 months.

* * * * *

20. Section 640.24 is amended by revising paragraph (b) to read as follows:

§ 640.24 Processing.

* * * * *

(b) Immediately after collection, the whole blood or plasma shall be held in storage between 20 and 24 °C, unless it must be transported from the collection center to the processing laboratory. During such transport, all reasonable methods shall be used to maintain the temperature as close as possible to a range between 20 and 24 °C until it arrives at the processing laboratory where it shall be held between 20 and 24 °C until the platelets are separated. The platelet concentrate shall be separated within the timeframe specified in the directions for use for the specific device used for the collection of the unit of whole blood or plasma.

* * * * *

§ 640.31 [Amended]

21. Section 640.31 *Suitability of donors* is amended by removing paragraph (c).

22. Section 640.32 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 640.32 Collection of source material.

(a) Whole blood shall be collected, transported, and stored as prescribed in § 640.4. * * *

* * * * *

23. Section 640.34 is amended by revising paragraphs (a) through (d), (e)(1) through (e)(3), and (g)(2) to read as follows:

§ 640.34 Processing.

(a) *Plasma*. Plasma shall be separated from the red blood cells and shall be stored at –18 °C or colder within the timeframe specified in the directions for use for the specific device after transfer to the final container, unless the product is to be stored as Liquid Plasma.

(b) *Fresh Frozen Plasma*. Fresh Frozen Plasma shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and minimal manipulation of the donor's tissue. The plasma shall be

separated from the red blood cells, frozen solid within the timeframe specified in the directions for use for the specific device, and stored at –18 °C or colder.

(c) *Liquid Plasma*. Liquid Plasma shall be separated from the red blood cells and shall be stored at a temperature of 1 to 6 °C within the timeframe specified in the directions for use for the specific device after filling the final container.

(d) *Platelet Rich Plasma*. Platelet Rich Plasma shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and manipulation of the donor's tissue. The plasma shall be separated from the red blood cells by centrifugation within the timeframe specified in the directions for use for the specific device after completion of the phlebotomy. The time and speed of centrifugation shall have been shown to produce a product with at least 250,000 platelets per microliter. The plasma shall be stored at a temperature between 20 and 24 °C, immediately after filling the final container. A gentle and continuous agitation of the product shall be maintained throughout the storage period, if stored at a temperature of 20 to 24 °C.

(e) * * *

(1) Platelets shall be separated as prescribed in subpart C of part 640, prior to freezing the plasma. The remaining plasma may be labeled as ''Fresh Frozen Plasma,'' if frozen within the timeframe specified in the directions for use for the specific device after filling the final container.

(2) Cryoprecipitated AHF shall be removed as prescribed in subpart F of part 640. The remaining plasma shall be labeled ''Plasma, Cryoprecipitate Reduced.''

(3) Plasma remaining after both Platelets and Cryoprecipitated AHF have been removed may be labeled ''Plasma, Cryoprecipitate Reduced.''

* * * * *

(g) * * *

(2) With the exception of Platelet Rich Plasma and Liquid Plasma the final product shall be inspected for evidence of thawing or breakage at the time of issuance, however, the containers need not be stored in a manner that shows evidence of thawing if records of continuous monitoring of the storage temperature establish that the temperature remained at –18 °C or colder. If continuous monitoring of the product is not available, the final product shall be stored in a manner that will show evidence of thawing and shall not be issued if there is any evidence of thawing.

* * * * *

§ 640.51 [Amended]

24. Section 640.51 *Suitability of donors* is amended by removing paragraph (c).

25. Section 640.52 is amended by revising paragraph (a) to read as follows:

§ 640.52 Collection of source material.

(a) Whole blood used as a source of Cryoprecipitated AHF shall be collected as prescribed in § 640.4. Whole blood from which both Platelets and Cryoprecipitated AHF is derived shall be maintained as required under § 640.24 until the platelets are removed.

* * * * *

26. Section 640.54 is amended by revising paragraph (a)(2) to read as follows:

§ 640.54 Processing.

(a) * * *

(2) The plasma shall be frozen solid after blood collection within the timeframe specified in the directions for use for the specific device. A combination of dry ice and organic solvent may be used for freezing: *Provided*, That the procedure has been shown not to cause the solvent to penetrate the container or leach plasticizer from the container into the plasma.

* * * * *

27. Section 640.56 is amended by revising the introductory text of paragraph (c) to read as follows:

§ 640.56 Quality control test for potency.

* * * * *

(c) The quality control test for potency may be performed by a clinical laboratory which meets the standards of the Clinical Laboratories Improvement Act of 1988 (CLIA) (42 U.S.C. 263a) and is qualified to perform potency tests for antihemophilic factor. Such arrangements must be approved by the Director, Center for Biologics Evaluation and Research, Food and Drug Administration. Such testing shall not be considered as divided manufacturing, as described in § 610.63 of this chapter, provided the following conditions are met:

* * * * *

28. Section 640.62 is revised to read as follows:

§ 640.62 Medical supervision.

A qualified licensed physician shall be available to attend to the donor within 15 minutes when donor suitability is being determined, immunizations are being made, whole blood is being collected, and red blood cells are being returned to the donor, except that during the administration of immunization red blood cells a qualified licensed physician shall be on the premises.

29. Section 640.63 is amended by revising paragraphs (c)(3), (c)(5), (c)(11), (c)(12), and (c)(13) to read as follows:

§ 640.63 Suitability of donor.

* * * * *

(c) * * *

(3) A blood hemoglobin level of no less than 12.5 grams of hemoglobin per 100 milliliters of blood or a hematocrit level of 38 percent;

* * * * *

(5) A total serum or total plasma protein of no less than 6.0 grams per 100 milliliters of blood;

* * * * *

(11) A history of viral hepatitis after the age of eleven;

(12) Freedom from a history of close contact within 12 months of donation with an individual having viral hepatitis;

(13) Freedom from a history of having received, within 12 months, human blood or any derivative of human blood which the Food and Drug Administration has advised the blood establishment is a possible source of viral hepatitis, except for specific immunization performed in accordance with § 640.66.

* * * * *

30. Section 640.65 is amended by revising paragraphs (b)(4) and (b)(5) and by adding paragraph (b)(8) to read as follows:

§ 640.65 Plasmapheresis.

* * * * *

(b) * * *

(4) The amount of whole blood, not including anticoagulant, removed from a donor during a manual plasmapheresis procedure or in any 2-day period shall not exceed 1,000 milliliters unless the donor's weight is 175 pounds or greater, in which case the amount of whole blood, not including anticoagulant, removed from the donor during a manual plasmapheresis procedure or in any 2-day period shall not exceed 1,200 milliliters.

(5) The amount of whole blood, not including anticoagulant, removed from a donor during a manual plasmapheresis procedure within a 7-day period shall not exceed 2,000 milliliters unless the donor's weight is 175 pounds or greater, in which case the amount of whole blood, not including

anticoagulant, removed from a donor during a manual plasmapheresis procedure within a 7-day period shall not exceed 2,400 milliliters.

* * * * *

(8) The volume of plasma collected during an automated plasmapheresis collection procedure shall be consistent with the volumes specifically approved by the Director, Center for Biologics Evaluation and Research, and collection shall not occur less than 2 days apart or more frequently than twice in a 7-day period.

31. Section 640.69 is amended by revising paragraph (d) to read as follows:

§ 640.69 General requirements.

* * * * *

(d) *Samples*. If samples are provided, they shall meet the following standards:

(1) Prior to filling, all samples shall be marked or identified so as to relate them directly to the donor of that unit of plasma.

(2) All samples shall be filled at the time the final product is prepared by the person who prepares the final product.

(3) All samples shall be representative of the contents of the final product or be collected from the donor at the time of filling the collection container.

(4) All samples shall be collected in a manner that does not contaminate the contents of the final container.

32. Section 640.71 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 640.71 Manufacturing responsibility.

(a) All steps in the manufacturing of Source Plasma, including donor examination, blood collection, plasmapheresis, laboratory testing, labeling, storage, and issuing shall be performed by personnel of the establishment licensed to manufacture Source Plasma, except that the following tests may be performed by personnel of an establishment licensed for blood and blood derivatives under section 351(a) of the Public Health Service Act, or by a clinical laboratory that meets the standards of the Clinical Laboratories Improvement Act of 1988 (CLIA) (42 U.S.C. 263a): *Provided*, The establishment or clinical laboratory is qualified to perform the assigned test(s).

* * * * *

33. Section 640.72 is amended by revising paragraph (a)(1) to read as follows:

§ 640.72 Records.

(a) * * *

(1) Documentation shall be available to ensure that the shipping temperature requirements of § 600.15 of this title and of § 640.74(b)(2) are being met for Source Plasma intended for manufacture into injectable products.

* * * * *

Dated: April 20, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 99–21292 Filed 8–18–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606 and 640

[Docket No. 98N–0673]

Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, and Source Plasma to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. FDA is taking this action as part of the agency's ''Blood Initiative'' in which FDA is reviewing and revising, when appropriate, its regulations, policies, guidance, and procedures related to blood, blood components, and Source Plasma. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**. FDA is publishing this companion proposed rule under FDA's usual procedure for notice and comment to provide a procedural framework to finalize the rule in the event the agency receives a significant adverse comment and withdraws the direct final rule.

DATES: Submit written comments on or before December 3, 1999. If FDA receives any significant adverse comment regarding this rule, FDA will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA then will proceed to respond to the comments under this proposed rule using the usual notice and comment procedures. Any parties interested in commenting on this document should do so at this time.

If FDA receives no significant adverse comments within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on the direct final rule ends. The direct final rule will be effective February 11, 2000.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Dano B. Murphy, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule will provide the procedural framework to finalize the rule in the event that the direct final rule receives any adverse comment and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received under this companion rule will also be considered as comments regarding the direct final rule. FDA is publishing the direct final rule because the rule contains noncontroversial changes, and FDA anticipates that it will receive no significant adverse comment.

A significant comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a rule change in addition to the rule would not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not subjects of a significant adverse comment.

If no significant adverse comment is received within the specified comment period, FDA will publish a document within 30 days after the comment period ends confirming that the direct final rule will be effective February 11, 2000. Additional information about FDA's direct rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

For a variety of reasons, FDA has decided to comprehensively review and, as necessary, revise its regulations, policies, guidance, and procedures related to the licensing and regulation of blood products. FDA is issuing this companion proposed rule and the direct final rule, published elsewhere in this issue of the **Federal Register**, as part of the agency's ''Blood Initiative'' in which FDA is reviewing and revising, when appropriate, its regulations, policies, guidance, and procedures related to blood, blood components, and Source Plasma. The ''Blood Initiative'' is discussed in detail in the preamble to the direct final rule. FDA emphasizes that for many of the changes discussed below, additional issues related to the regulations now being amended continue to be under consideration by the agency. Further, more substantive changes may be proposed at a later date. Accordingly, any comment recommending an additional change to these regulations will not be considered to be an ''adverse comment'' unless the comment demonstrates that the change being made in the direct final rule represents a major departure from current regulations or accepted industry standards, or cannot be implemented without additional amendments to the regulations.

II. Legal Authority

FDA is proposing to issue this new rule under the biological product and communicable disease provisions of the Public Health Service Act (the PHS Act) (42 U.S.C. 262–264) and the drug, device, and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 331, 351–353, 355, 360, 360j, 371, and 374). Under these provisions of the PHS Act and the act, FDA has the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, potent, and properly labeled and to prevent the introduction, transmission, and spread of communicable disease.

III. Highlights of the Proposed Rule

FDA is proposing to amend the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, and Source Plasma to be more consistent with current practices and to remove unnecessary or outdated requirements. As, previously discussed, FDA is also issuing these amendments as a direct final rule because the agency

has concluded they are noncontroversial and that there is little likelihood that there will be comments opposing the rule. FDA emphasizes that for many of the changes discussed in this document, additional issues related to the regulations now being amended continue to be under consideration by the agency. Further, more substantive changes may be proposed at a later date. Accordingly, any comment recommending additional changes to these regulations will not be considered to be an ''adverse comment'' unless the comment demonstrates that the change being made in the direct final rule represents a major departure from current regulations or accepted industry standards, or cannot be implemented without additional amendments to the regulation. Below FDA is identifying each of the changes included in the proposed rule.

Part 606 (21 CFR part 606) would be amended as follows:

Section 606.3, Definitions, would be amended to update the definitions provided in the section for consistency with current practice and usages.

The definition of ''Component'' in proposed § 606.3(c), would be amended to clarify that blood is obtained from a single donor and would no longer include the wording ''single-donor unit.'' This change is to clarify that blood components may be collected by means other than separation from a unit of whole blood, such as by automated plasmapheresis.

The definition of ''Plasmapheresis'' in proposed § 606.3(e), would be amended by removing the restriction that plasmapheresis may be ''immediately repeated, once'' because current automated plasmapheresis collection practices often use more than two cycles of collection.

The definition of ''Plateletpheresis'' in proposed § 606.3(f) would be amended to provide for the common practice of collecting plasma as a by-product of a plateletpheresis procedure in lieu of returning all of the residual plasma to the donor.

The definition of ''Compatibility testing'' in proposed § 606.3(j) would be amended by removing the reference to serological tests and making the definition more general to apply to all tests performed to establish the matching of a donor's blood or blood components with that of a recipient. This change will provide for current practices used in compatibility testing, such as the electronic crossmatch and the immediate spin crossmatch.

Section 606.100(b) and (d) would be amended to reflect changes in terminology, requirements for testing, and availability of standard operating procedures (SOP's) to be consistent with current practices. Section 606.100(b) would also be amended by removing the references to homologous and autologous transfusion because subpart F of part 606 applies to all blood products intended for transfusion. In addition, the phrase ''unless this is impractical'' would be removed because it is current good manufacturing practice (CGMP) to make the applicable SOP's available in all areas where procedures are performed. Section 606.100(b)(7) would be amended by removing ''including testing for hepatitis B surface antigen as prescribed in § 610.40 of this chapter'' because other tests, in addition to tests for hepatitis B surface antigen, are now required and specific reference to this test is unnecessary. Section 606.100(b)(18) would be amended by removing the bracketed term ''salvaged'' because its use in § 606.100 is inconsistent with the use of ''salvaged plasma'' in § 640.76 (21 CFR 640.76). Section 606.100(d) would be amended by removing references to specific organizations because any SOP's meeting FDA requirements would be acceptable, regardless of their source, and because FDA cannot assure that SOP's adopted by particular organizations remain in compliance with FDA regulatory requirements.

Section 606.121(a) would be amended by removing the reference that the ''Guideline for Uniform Labeling of Blood and Blood Components'' is available from the Docket Management Branch as this is no longer the appropriate office from which to request this document and by removing the reference to the American Blood Commission because the organization no longer exists.

Section 606.121(d)(2) specifies the color requirements for printing the container label and would be amended by adding ''or in solid black'' because some blood centers use on-demand printers for printing labels that do not have the capability to print in multiple colors.

Section 606.121(e)(1)(ii) prescribes the specific anticoagulants that shall be identified on the container label. Section 606.121(e)(1)(ii) would be amended by removing the references to the names of specific anticoagulants. This change will allow for more flexibility for the acceptance and use of new anticoagulants or changes in nomenclature of existing anticoagulants without requiring amendments to the regulations.

Section 606.122(f) specifies the warning statement required in the instruction circular and would be amended by removing the reference to ''hepatitis'' and adding ''infectious agents'' to include a reference to the additional infectious disease marker tests routinely performed on blood and blood components because the product intended for transfusion carries the risk of transmitting other infectious agents.

Section 606.122(n)(4) specifies that the instruction circular for cryoprecipitated AHF shall contain instructions to thaw the product at a temperature of 37 °C and would be changed to allow instructions for thawing between 30 and 37 °C, permitting more flexibility in the preparation of the component.

Section 606.151(b) would be amended, consistent with current accepted practices, to permit SOP's to include use of recipient serum samples less than 3-days old for compatibility testing if the recipient has been pregnant or transfused within the proceeding 3 months.

Section 606.151(c) describes compatibility testing and would be amended by changing ''the testing of the donor's cells with the recipient's serum'' to ''the testing of the donor's cell type with the recipient's serum type'' and by replacing ''agglutinating, coating, and hemolytic antibodies, which shall include the antiglobulin method'' with ''incompatibility.'' This change is intended to accommodate the use of such procedures as an immediate spin crossmatch and an electronic crossmatch.

Section 606.151(e) would be amended by changing ''by the physician requesting the procedure'' to ''by a physician'' to take into account that a patient may have more than one physician in attendance at any time.

Section 606.160(b)(2)(v) would be amended by changing ''person(s) responsible'' to ''the person(s) performing the procedure'' to clarify that the person(s) performing the labeling procedure is responsible for documenting the performance of that procedure.

Section 606.170(b) would be amended by removing ''telegraph'' and adding ''facsimile, express mail, or electronically transmitted mail'' to the possible methods by which the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, shall be notified of a complication of blood collection or transfusion resulting in a fatality.

Part 640 (21 CFR part 640) would be amended as follows:

Section 640.2(b) would be removed because Whole Blood collection in open systems is no longer acceptable or has

it being performed for many years. Section 640.2(d) is removed. In § 640.2 paragraphs (c), (e), and (f) would be redesignated as paragraphs (b), (c), and (d), respectively. Redesignated paragraphs (b) and (c)(2) would be revised by removing references to the original blood container because, to be consistent with current accepted practices such as washing, freezing, deglycerolization, and division of units using sterile connecting devices, the original blood container may, in many cases, no longer be the final container.

Section 640.3(b) would be amended by adding a reference to autologous donations to permit the collection of autologous Whole Blood at intervals of less than 8 weeks, consistent with the current practice of shorter time intervals between collections of blood and blood components from donors participating in autologous collection programs. Section 640.3(b)(3) would be amended to provide hematocrit and hemoglobin values to be used when determining whether a potential donor can donate Whole Blood, by adding to the end of the current paragraph ''or a hematocrit value of 38 percent, and for autologous donations, a blood hemoglobin level which shall be demonstrated to be no less than 11.0 g of hemoglobin per 100 mL of blood or a hematocrit value of 33 percent.'' The acceptable hemoglobin and hematocrit values for autologous donors are consistent with current industry practice and the American Association of Blood Banks technical manual, 12th edition.

Sections 640.3(c)(1) and 640.63(c)(11) would be amended by inserting ''after the age of eleven'' after the term ''hepatitis'' because establishments may collect Whole Blood from donors who have a history of hepatitis prior to age eleven to be consistent with recommendations in the FDA memorandum dated April 23, 1992, entitled '' Exemptions to Permit Persons with a History of Viral Hepatitis Before the Age of Eleven to Serve as Donors of Whole Blood and Plasma: Alternative Procedure'' (21 CFR 640.120). Additional issues concerning donors who have a history of viral hepatitis continued to be reviewed by the agency and may be addressed in future rulemaking objectives.

Sections 640.3(c)(2) and 640.63(c)(12) would be amended by changing the deferral period for donors of Whole Blood who have had close contact with an individual having viral hepatitis from ''six months'' to ''12 months.'' Similarly, §§ 640.3(c)(3) and 640.63(c)(13) would be amended by changing the deferral period from ''six months'' to ''12 months'' for donors of Whole Blood who received human blood, or any derivative of human blood which the Food and Drug Administration has identified as a possible source of viral hepatitis. These changes are consistent with recommendation made in the FDA memoranda dated April 23, 1992, entitled ''Revised Recommendations for the Prevention of Human Immunodeficiency Virus Transmission by Blood and Blood Products and Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV).'' In addition, §§ 640.3(c)(3) and 640.63(c)(13) would be amended by changing the reference from a ''licensed establishment'' to a ''blood establishment'' to clarify that the regulation applies to all establishments engaged in the collection of blood and blood products.

Sections 640.3(e), 640.31(c), and 640.51(c) would be removed because FDA has concluded that it is no longer necessary to defer donors participating in red blood cell immunization programs. Previously, donors participating in red blood cell immunization programs were deferred for 12 months because fresh red blood cells were used to immunize donors. Red blood cells now used in immunization programs are carefully screened and quarantined thereby minimizing the risk of transmitting known infectious agents. See FDA memorandum dated March 14, 1995, entitled ''Revised Recommendations for Red Blood Cell Immunization Programs for Source Plasma Donors'' for additional information about current red blood cell immunization practices.

Section 640.4(b) would be amended by removing the word ''clinic'' and replacing it with the word ''center'' to reflect current terminology and by changing the word ''licensed'' to ''blood'' to clarify that the regulation applies to all blood establishments engaged in the collection of blood and blood products. Section 640.4(d) would be amended by removing the reference to the specific anticoagulant formulae. Section 640.4(d)(1) through (d)(4) would be removed because FDA has determined it is unnecessary to provide specific formulae for anticoagulant solutions in the regulations and that manufacturers should be able to use any anticoagulant approved by FDA for such use.

Sections 640.13(a), 640.22(a), 640.32(a), and 640.52(a) would be amended to delete references to § 640.4(d)(2) and (h), which would be being removed. Section 640.4(g)(5) would be changed to include the use of different anticoagulants in segments for compatibility testing to be consistent with the use of different approved anticoagulants in the manufacture of blood and blood products. Section 640.4(h) would be removed because heparin anticoagulant solutions are no longer used for the routine collection of blood.

Section 640.5(c) would be amended to be consistent with current Rh factor testing practices by removing ''and for other Rh-Hr factors,'' because these tests are not routinely performed. The section would also be changed to specify that blood testing negative using Anti-D Blood Grouping Reagents may only be labeled ''Rh Negative'' if the confirmatory testing includes tests for weak expressions of D. These changes would be made to be consistent with current accepted practices which designate that tests for weak expressions of D be performed and the product labeled consistent with the results of those tests.

Sections 640.6(c) and 640.15(c) would be removed because the use of more modern methods of manufacturing and equipment have eliminated the use of pilot tubes attached to the blood units. In § 640.15 paragraph (d) is redesignated as paragraph (c).

Section 640.16(a) would be amended by inserting ''or additive solution'' after ''cryoprotective substance'' to reflect an additional procedure for prolonging shelf life now in use in which all the plasma is removed from a unit of blood.

Section 640.16(b) would be amended by removing all but the first sentence. The removed text describes blood collection procedures to be followed when using open vented systems. Use of open vented systems is no longer consistent with CGMP and has not been used for many years.

All references to ''pilot tubes'' and ''pilot samples'' would be replaced with the words ''sample(s)'' or ''segment(s)'' to reflect current terminology for various testing specimens. The following sections would be amended by replacing ''pilot tubes,'' ''pilot samples,'' or ''pilot sample tubes'' with ''segments'' or ''samples'' as appropriate in §§ 640.2(e)(1), 640.4(g) introductory text, and paragraphs (g)(1), (g)(2), (g)(4), and (g)(5), 640.5, 640.15(a) through (c), and 640.69(d) introductory text, and paragraphs (d)(1) through (d)(4).

Section 640.23(a) would be amended to include the preparation of Platelets prepared by automated collection procedures and to allow the group and typing tests performed on Platelets prepared by apheresis to be valid for a

period not to exceed 3 months, thereby, eliminating the necessity of repeat testing of blood samples from donors participating in frequent plasmapheresis collection procedures.

Section 640.24(b) would be amended by changing the time period for separation of the platelet concentrate from ''4 hours'' to ''within the time period specified in the directions for use for the specific device.'' Similar changes would be made to the timeframe for the storage of plasma that is set forth in § 640.34(a) through (d) and (e)(1) and the freezing of plasma set forth in § 640.54(a)(2). These changes, consistent with current accepted practices, permit more flexibility by permitting different timeframes depending on the particular blood collection device being used.

Sections 640.25(b) and 640.56(a) would be amended to require testing only in those months in which blood products would be prepared for use. This eliminates the need for performing quality control procedures during those months when product is not being manufactured.

Sections 640.25(c), 640.56(c), and 640.71(a) would be amended to update references to cite the ''Clinical Laboratories Improvement Amendments of 1988 (CLIA)'' consistent with nomenclature in the regulations implementing CLIA in 42 CFR part 493.

Section 640.34(d) would be amended by removing the reference to storing platelet rich plasma at temperatures between 1 and 6 °C because storage at such temperatures adversely affects platelet function.

Section 640.34(e)(2) and (e)(3) would be amended to include the proper name of the product ''Plasma, Cryoprecipitate Reduced'' as per recommendations of the Blood Products Advisory Committee at the meeting of September 18 and 19, 1997. Section 640.34(g)(2) would be amended to permit for proof of continuous monitoring of the temperature to be within acceptable ranges for the product as an alternative to requiring the storing of the product in a manner to show evidence of thawing. FDA believes that, with current technology, monitoring systems of freezers used for storage are adequately sensitive and reliable to detect any significant rise in storage temperature.

Section 640.62 requiring that a qualified licensed physician be on the premises when donor suitability is being determined would be amended to require a qualified licensed physician to be physically available on the premises, or be available to attend to the donor within 15 minutes, when a pheresis procedure is being performed, for consultation and management of donor adverse reactions, except that the qualified licensed physician shall be physically available on the premises when red blood cell immunizations are being performed. FDA has determined that a qualified licensed physician must always be readily available, if needed, and shall be on the premises for red blood cell immunizations.

Section 640.63(c)(3) would be amended by adding at the end of the sentence ''or a hematocrit level of 38 percent,'' which is equivalent to a hemoglobin level of 12.5 grams per 100 milliliters of blood, to be consistent with current accepted practices.

Section 640.63(c)(5) would be amended by adding ''or total plasma'' after ''A total serum'' to be consistent with current accepted practice of using a capillary tube coated with anticoagulant for fingerstick sample collection.

Section 640.65(b)(4) would be amended by changing ''in any 48-hour period'' to ''2-day'' to permit more flexibility in scheduling donor appointments and by adding the word ''manual'' to the phrases ''during a plasmapheresis procedure'' to clarify that the regulation applies to a manual plasmapheresis collection procedure, but does not apply to automated apheresis.

Section 640.65(b)(5) would be amended by adding ''during a manual plasmapheresis procedure'' after the phrases ''removed from the donor'' to clarify that the regulation applies to a manual plasmapheresis collection procedure, but does not apply to automated apheresis.

Section 640.65(b)(8) would be added to address the collection of Source Plasma using automated collection devices. The regulation describes the frequency of collection consistent with § 640.65(b)(4) and (b)(5) and the volume of plasma to be collected during such procedures consistent with the plasma collection volumes approved for each device and with recommendations included in the FDA memorandum to all plasma establishments dated November 4, 1992, entitled ''Volume Limits for Automated Collection of Source Plasma.''

Section 640.72(a)(1) would be amended by replacing ''compiled every 3 months'' with ''shall be available'' to eliminate the necessity of compiling documents for review at specified periods of time.

IV. Analysis of Impacts

A. Review Under Executive Order 12866 and the Regulatory Flexibility Act and the Unfunded Mandates Reform Act of 1995

FDA has examined the impact of the companion proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U. S. C. 601–612), and the Unfunded Mandates Reform Act of 1995 (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 impact; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. This proposed rule is not a significant regulatory action as defined by the Executive Order and therefore is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options to minimize any significant impact of a rule on small business entities. Because the proposed rule amendments have no compliance costs and do not result in any new requirements, the agency certifies that the proposed rule will not have a significant negative economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required. This proposed rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, and tribal governments in the aggregate, or by the private sector in any 1 year.

B. Environmental Impact

The agency has determined under 21 CFR 25.31(j) 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.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Request for Comments

Interested persons may, on or before December 3, 1999, submit to the Docket Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and authority delegated by the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 606 and 640 be amended as follows:

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

1. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

2. Section 606.3 is amended by revising paragraphs (c), (e), (f), and (j) to read as follows:

§ 606.3 Definitions.

* * * * *

(c) *Component* means that part of a single-donor's blood separated by physical or mechanical means.

* * * * *

(e) *Plasmapheresis* means the procedure in which blood is removed from the donor, the plasma is separated from the formed elements and at least the red blood cells are returned to the donor.

(f) *Plateletpheresis* means the procedure in which blood is removed from a donor, a platelet concentrate is separated, and the remaining formed elements are returned to the donor along with a portion of the residual plasma.

* * * * *

(j) *Compatibility testing* means the tests performed to establish the matching of a donor's blood or blood components with that of a potential recipient.

3. Section 606.100 is amended by revising the introductory text of paragraphs (b) and (d), and by revising paragraphs (b)(7) and (b)(18) to read as follows:

§ 606.100 Standard operating procedures.

* * * * *

(b) Written standard operating procedures shall be maintained and shall include all steps to be followed in the collection, processing, compatibility testing, storage, and distribution of blood and blood components for transfusion and further manufacturing purposes. Such procedures shall be available to the personnel for use in the areas where the procedures are performed. The written standard operating procedures shall include, but are not limited to, descriptions of the following, when applicable:

* * * * *

(7) All tests and repeat tests performed on blood and blood components during manufacturing.

* * * * *

(18) Procedures for preparing recovered plasma, if performed, including details of separation, pooling, labeling, storage, and distribution.

* * * * *

(d) In addition to the requirements of this subpart and in conformity with this section, any facility may utilize current standard operating procedures such as the manuals of the organizations, as long as such specific procedures are consistent with, and at least as stringent as, the requirements contained in this part.

* * * * *

4. Section 606.121 is amended by revising paragraphs (a), (d)(2), and (e)(1)(ii) to read as follows:

§ 606.121 Container label.

(a) The container label requirements are designed to facilitate the use of a uniform container label for blood and blood components (except Source Plasma) by all blood establishments.

* * * * *

(d) * * *

(2) The proper name of the product, any appropriate modifier(s), the donor classification statement, and the statement ''properly identify intended recipient'' shall be printed in solid red or in solid black.

* * * * *

(e) * * *

(1) * * *

(ii) The name of the applicable anticoagulant immediately preceding and of no less prominence than the proper name approved for use by the Director, Center for Biologics Evaluation and Research.

* * * * *

5. Section 606.122 is amended by revising paragraphs (f) and (n)(4) to read as follows:

§ 606.122 Instruction circular.

* * * * *

(f) The statements: ''Warning. The risk of transmitting infectious agents is present. Careful donor selection and available laboratory tests do not eliminate the hazard.''

* * * * *

(n) * * *

(4) Instructions to thaw the product for no more than 15 minutes at a temperature between 30 and 37 °C.

* * * * *

6. Section 606.151 is amended by revising paragraphs (b), (c), and (e) to read as follows:

§ 606.151 Compatibility testing.

* * * * *

(b) The use of fresh recipient serum samples less than 3-days old for all pretransfusion testing if the recipient has been pregnant or transfused within the previous 3 months.

(c) The testing of the donor's cell type with the recipient's serum type by a method that will demonstrate incompatibility.

* * * * *

(e) Procedures to expedite transfusion in life-threatening emergencies. Records of all such incidents shall be maintained, including complete documentation justifying the emergency action, which shall be signed by a physician.

7. Section 606.160 is amended by revising paragraph (b)(2)(v) to read as follows:

§ 606.160 Records.

* * * * *

(b) * * *

(2) * * *

(v) Labeling, including initials of the person(s) performing the procedure.

* * * * *

8. Section 606.170 is amended by revising paragraph (b) to read as follows:

§ 606.170 Adverse reaction file.

* * * * *

(b) When a complication of blood collection or transfusion is confirmed to be fatal, the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, shall be notified by telephone,

facsimile, express mail, or electronically transmitted mail as soon as possible; a written report of the investigation shall be submitted to the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, within 7 days after the fatality by the collecting facility in the event of a donor reaction, or by the facility that performed the compatibility tests in the event of a transfusion reaction.

(Information collection requirements approved by the Office of Management and Budget under control number 0910–0116)

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

9. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

10. Section 640.2 is amended by removing paragraphs (b) and (d), by redesignating paragraphs (c), (e), and (f) as paragraphs (b), (c), and (d), respectively, and by revising newly redesignated paragraphs (b) and (c)(2) to read as follows:

§ 640.2 General requirements.

* * * * *

(b) *Blood container.* The blood container shall not be entered prior to issue for any purpose except for blood collection. Such container shall be uncolored and transparent to permit visual inspection of the contents and any closure shall be such as will maintain an hermetic seal and prevent contamination of the contents. The container material shall not interact with the contents under the customary conditions of storage and use, in such a manner as to have an adverse effect upon the safety, purity, or potency of the blood.

(c) * * *

(2) A segment is properly attached and has not been removed, except that blood lacking a properly attached segment may be reissued in an emergency provided it is accompanied by instructions for sampling and for use within 6 hours after entering the container for sampling;

* * * * *

11. Section 640.3 is amended by revising the introductory text of paragraph (b), by revising paragraphs (b)(3), (c)(1), (c)(2), and (c)(3) and by removing and reserving paragraph (e) to read as follows:

§ 640.3 Suitability of donor.

* * * * *

(b) *Qualifications of donor; general.* Except as provided in paragraph (f) of this section and for autologous donations, a person may not serve as a source of Whole Blood more than once in 8 weeks. In addition, donors shall be in good health, as indicated in part by:

* * * * *

(3) For allogeneic donors, a blood hemoglobin level which shall be demonstrated to be no less than 12.5 grams (g) of hemoglobin per 100 milliliters (mL) of blood; or a hematocrit value of 38 percent, and for autologous donors, a blood hemoglobin level which shall be demonstrated to be no less than 11.0 g of hemoglobin per 100 mL of blood or a hematocrit value of 33 percent.

* * * * *

(c) * * *

(1) A history of viral hepatitis after the age of eleven;

(2) A history of close contact within 12 months of donation with an individual having viral hepatitis;

(3) A history of having received within 12 months of donation, human blood or any derivative of human blood which the Food and Drug Administration has advised the blood establishment is a possible source of viral hepatitis.

* * * * *

12. Section 640.4 is amended by removing paragraphs (d)(1) through (d)(4) and (h), by redesignating paragraph (i) as paragraph (h), and revising paragraphs (b) and (d), the introductory text of paragraph (g), and paragraphs (g)(1), (g)(2), (g)(4), and (g)(5) to read as follows:

§ 640.4 Collection of the blood.

* * * * *

(b) *The donor center.* The pertinent requirements of §§ 600.10 and 600.11 of this chapter shall apply at both the blood establishment and at any other place where the bleeding is performed.

* * * * *

(d) *The anticoagulant solution.* The anticoagulant solution shall be sterile and pyrogen-free. Anticoagulant solutions shall be compounded and used according to a formula approved by the Director, Center for Biologics Evaluation and Research.

* * * * *

(g) *Samples for laboratory tests.* Samples for laboratory tests shall meet the following standards:

(1) One or more segments shall be provided with each unit of blood when issued or reissued except as provided in § 640.2(e)(2) and all segments shall be from the donor who is the source of the unit of blood.

(2) All samples for laboratory tests performed by the manufacturer and all segments accompanying a unit of blood shall be collected at the time of filling the original blood container.

* * * * *

(4) All segments accompanying a unit of blood shall be attached to the whole blood container before blood collection, in a tamper proof manner that will conspicuously indicate removal and reattachment.

(5) Segments for compatibility testing shall contain blood mixed with the appropriate anticoagulant.

* * * * *

13. Section 640.5 is amended by revising the introductory text and paragraph (c) to read as follows:

§ 640.5 Testing the blood.

All laboratory tests shall be made on a specimen of blood taken from the donor at the time of collecting the unit of blood, and these tests shall include the following:

* * * * *

(c) *Determination of the Rh factors.* Each container of Whole Blood shall be classified as to Rh type on the basis of tests done on the sample. The label shall indicate the extent of typing and the results of all tests performed. If the test, using Anti-D Blood Grouping Reagent, is positive, the container may be labeled ''Rh Positive''. If this test is negative, the results shall be confirmed by further testing which shall include tests for the Rh_o variant (D^u). Blood may be labeled ''Rh Negative'' if further testing is negative. Units testing positive after additional more specific testing shall be labeled as ''Rh Positive.'' Only Anti-Rh Blood Grouping Reagents licensed under, or that otherwise meet the requirements of, the regulations of this subchapter shall be used, and the technique used shall be that for which the reagent is specifically designed to be effective.

* * * * *

§ 640.6 [Amended]

14. Section 640.6 *Modifications of Whole Blood* is amended by removing paragraph (c).

15. Section 640.13 is amended by revising paragraph (a) to read as follows:

§ 640.13 Collection of the blood.

(a) The source blood shall be collected as prescribed in § 640.4.

* * * * *

16. Section 640.15 is revised to read as follows:

§ 640.15 Samples for testing.

Samples collected in integral tubing shall meet the following standards:

(a) One or more segments of either the original blood or of the Red Blood Cells being processed shall be provided with each unit of Red Blood Cells when issued or reissued.

(b) Before they are filled, all segments shall be marked or identified so as to relate them to the donor of that unit of red cells.

(c) All segments accompanying a unit of Red Blood Cells shall be filled at the time the blood is collected or at the time the final product is prepared.

17. Section 640.16 is amended by revising paragraphs (a) and (b) to read as follows:

§ 640.16 Processing.

(a) *Separation*. Within the timeframe specified in the directions for the use of the specific devices, Red Blood Cells may be prepared either by centrifugation, done in a manner that will not tend to increase the temperature of the blood, or by normal undisturbed sedimentation. A portion of the plasma sufficient to insure optimal cell preservation shall be left with the red cells except when a cryoprotective substance or additive solution is added for prolonged storage.

(b) *Sterile system*. All surfaces that come in contact with the red cells shall be sterile and pyrogen-free.

* * * * *

18. Section 640.22 is amended by revising paragraph (a) to read as follows:

§ 640.22 Collection of source material.

(a) Whole blood used as the source of Platelets shall be collected as prescribed in § 640.4.

* * * * *

19. Section 640.23 is amended by revising paragraph (a) to read as follows:

§ 640.23 Testing the blood.

(a) Blood from which plasma is separated for the preparation of Platelets or Platelets, Pheresis shall be tested as prescribed in §§ 610.40 and 610.45 of this chapter and § 640.5(a), (b), and (c). Results of tests performed in accordance with § 640.5(b) and (c) for Platelets, Pheresis products shall be valid for a period not to exceed 3 months.

* * * * *

20. Section 640.24 is amended by revising paragraph (b) to read as follows:

§ 640.24 Processing.

* * * * *

(b) Immediately after collection, the whole blood or plasma shall be held in storage between 20 and 24 °C, unless it must be transported from the collection center to the processing laboratory. During such transport, all reasonable methods shall be used to maintain the temperature as close as possible to a range between 20 and 24 °C until it arrives at the processing laboratory where it shall be held between 20 and 24 °C until the platelets are separated. The platelet concentrate shall be separated within the timeframe specified in the directions for use for the specific device used for the collection of the unit of whole blood or plasma.

* * * * *

§ 640.31 [Amended]

21. Section 640.31 *Suitability of donors* is amended by removing paragraph (c).

22. Section 640.32 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 640.32 Collection of source material.

(a) Whole blood shall be collected, transported, and stored as prescribed in § 640.4. * * *

* * * * *

23. Section 640.34 is amended by revising paragraphs (a) through (d), (e)(1) through (e)(3), and (g)(2) to read as follows:

§ 640.34 Processing.

(a) *Plasma*. Plasma shall be separated from the red blood cells and shall be stored at –18 °C or colder within the timeframe specified in the directions for use for the specific device after transfer to the final container, unless the product is to be stored as Liquid Plasma.

(b) *Fresh Frozen Plasma*. Fresh Frozen Plasma shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and minimal manipulation of the donor's tissue. The plasma shall be separated from the red blood cells, frozen solid within the timeframe specified in the directions for use for the specific device, and stored at –18 °C or colder.

(c) *Liquid Plasma*. Liquid Plasma shall be separated from the red blood cells and shall be stored at a temperature of 1 to 6 °C within the timeframe specified in the directions for use for the specific device after filling the final container.

(d) *Platelet Rich Plasma*. Platelet Rich Plasma shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and manipulation of the donor's tissue. The plasma shall be separated from the red blood cells by centrifugation within the timeframe specified in the directions for use for the specific device after completion of the phlebotomy. The time and speed of centrifugation shall have been shown to produce a product with at least 250,000 platelets per microliter. The plasma shall be stored at a temperature between 20 and 24 °C, immediately after filling the final container. A gentle and continuous agitation of the product shall be maintained throughout the storage period, if stored at a temperature of 20 to 24 °C.

(e) * * *

(1) Platelets shall be separated as prescribed in subpart C of part 640, prior to freezing the plasma. The remaining plasma may be labeled as ''Fresh Frozen Plasma,'' if frozen within the timeframe specified in the directions for use for the specific device after filling the final container.

(2) Cryoprecipitated AHF shall be removed as prescribed in subpart F of part 640. The remaining plasma shall be labeled ''Plasma, Cryoprecipitate Reduced.''

(3) Plasma remaining after both Platelets and Cryoprecipitated AHF have been removed may be labeled ''Plasma, Cryoprecipitate Reduced.''

* * * * *

(g) * * *

(2) With the exception of Platelet Rich Plasma and Liquid Plasma the final product shall be inspected for evidence of thawing or breakage at the time of issuance, however, the containers need not be stored in a manner that shows evidence of thawing if records of continuous monitoring of the storage temperature establish that the temperature remained at –18 °C or colder. If continuous monitoring of the product is not available, the final product shall be stored in a manner that will show evidence of thawing and shall not be issued if there is any evidence of thawing.

* * * * *

§ 640.51 [Amended]

24. Section 640.51 *Suitability of donors* is amended by removing paragraph (c).

25. Section 640.52 is amended by revising paragraph (a) to read as follows:

§ 640.52 Collection of source material.

(a) Whole blood used as a source of Cryoprecipitated AHF shall be collected as prescribed in § 640.4. Whole blood from which both Platelets and Cryoprecipitated AHF is derived shall be maintained as required under § 640.24 until the platelets are removed.

* * * * *

26. Section 640.54 is amended by revising paragraph (a)(2) to read as follows:

§ 640.54 Processing.

(a) * * *

(2) The plasma shall be frozen solid after blood collection within the timeframe specified in the directions for use for the specific device. A combination of dry ice and organic solvent may be used for freezing: *Provided*, That the procedure has been shown not to cause the solvent to penetrate the container or leach plasticizer from the container into the plasma.

* * * * *

27. Section 640.56 is amended by revising the introductory text of paragraph (c) to read as follows:

§ 640.56 Quality control test for potency.

* * * * *

(c) The quality control test for potency may be performed by a clinical laboratory which meets the standards of the Clinical Laboratories Improvement Act of 1988 (CLIA) (42 U.S.C. 263a) and is qualified to perform potency tests for antihemophilic factor. Such arrangements must be approved by the Director, Center for Biologics Evaluation and Research, Food and Drug Administration. Such testing shall not be considered as divided manufacturing, as described in § 610.63 of this chapter, provided the following conditions are met:

* * * * *

28. Section 640.62 is revised to read as follows:

§ 640.62 Medical supervision.

A qualified licensed physician shall be available to attend to the donor within 15 minutes when donor suitability is being determined, immunizations are being made, whole blood is being collected, and red blood cells are being returned to the donor, except that during the administration of immunization red blood cells a qualified licensed physician shall be on the premises.

29. Section 640.63 is amended by revising paragraphs (c)(3), (c)(5), (c)(11), (c)(12), and (c)(13) to read as follows:

§ 640.63 Suitability of donor.

* * * * *

(c) * * *

(3) A blood hemoglobin level of no less than 12.5 grams of hemoglobin per 100 milliliters of blood or a hematocrit level of 38 percent;

* * * * *

(5) A total serum or total plasma protein of no less than 6.0 grams per 100 milliliters of blood;

* * * * *

(11) A history of viral hepatitis after the age of eleven;

(12) Freedom from a history of close contact within 12 months of donation with an individual having viral hepatitis;

(13) Freedom from a history of having received, within 12 months, human blood or any derivative of human blood which the Food and Drug Administration has advised the blood establishment is a possible source of viral hepatitis, except for specific immunization performed in accordance with § 640.66.

* * * * *

30. Section 640.65 is amended by revising paragraphs (b)(4) and (b)(5) and by adding paragraph (b)(8) to read as follows:

§ 640.65 Plasmapheresis.

* * * * *

(b) * * *

(4) The amount of whole blood, not including anticoagulant, removed from a donor during a manual plasmapheresis procedure or in any 2-day period shall not exceed 1,000 milliliters unless the donor's weight is 175 pounds or greater, in which case the amount of whole blood, not including anticoagulant, removed from the donor during a manual plasmapheresis procedure or in any 2-day period shall not exceed 1,200 milliliters.

(5) The amount of whole blood, not including anticoagulant, removed from a donor during a manual plasmapheresis procedure within a 7-day period shall not exceed 2,000 milliliters unless the donor's weight is 175 pounds or greater, in which case the amount of whole blood, not including anticoagulant, removed from a donor during a manual plasmapheresis procedure within a 7-day period shall not exceed 2,400 milliliters.

* * * * *

(8) The volume of plasma collected during an automated plasmapheresis collection procedure shall be consistent with the volumes specifically approved by the Director, Center for Biologics Evaluation and Research, and collection shall not occur less than 2 days apart or more frequently than twice in a 7-day period.

31. Section 640.69 is amended by revising paragraph (d) to read as follows:

§ 640.69 General requirements.

* * * * *

(d) *Samples*. If samples are provided, they shall meet the following standards:

(1) Prior to filling, all samples shall be marked or identified so as to relate them directly to the donor of that unit of plasma.

(2) All samples shall be filled at the time the final product is prepared by the person who prepares the final product.

(3) All samples shall be representative of the contents of the final product or be collected from the donor at the time of filling the collection container.

(4) All samples shall be collected in a manner that does not contaminate the contents of the final container.

32. Section 640.71 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 640.71 Manufacturing responsibility.

(a) All steps in the manufacturing of Source Plasma, including donor examination, blood collection, plasmapheresis, laboratory testing, labeling, storage, and issuing shall be performed by personnel of the establishment licensed to manufacture Source Plasma, except that the following tests may be performed by personnel of an establishment licensed for blood and blood derivatives under section 351(a) of the Public Health Service Act, or by a clinical laboratory that meets the standards of the Clinical Laboratories Improvement Act of 1988 (CLIA) (42 U.S.C. 263a): *Provided*, The establishment or clinical laboratory is qualified to perform the assigned test(s).

* * * * *

33. Section 640.72 is amended by revising paragraph (a)(1) to read as follows:

§ 640.72 Records.

(a) * * *

(1) Documentation shall be available to ensure that the shipping temperature requirements of § 600.15 of this title and of § 640.74(b)(2) are being met for Source Plasma intended for manufacture into injectable products.

* * * * *

Dated: April 20, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 99–21293 Filed 8–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. 98N–0815]

Plasma Derivatives and Other Blood-Derived Products; Requirements for Tracking and Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to propose regulations requiring that certain blood-derived products, including certain plasma derivatives, be tracked from a U.S. licensed manufacturer, through the distribution network, to any patient having custody of the product. Additionally, FDA intends to require notification of consignees and patients having custody of a blood-derived product or an analogous recombinant product in the event the product is associated with a potential increased risk of transmitting a communicable disease, as determined by FDA or by a U.S. licensed manufacturer. The regulations would also apply to any blood-derived product which, in the future, may be routinely dispensed to the patient and held by the patient prior to administration. FDA intends to take this action to help ensure notification of patients having custody of blood-derived products when such products may be associated with a potential increased risk of transmitting a communicable disease so that patients may make informed, appropriate decisions. FDA is soliciting comments and information from interested persons concerning the subject matter of the proposed regulations.

DATES: Submit written comments by November 17, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Steven F. Falter, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 208520–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In a July 25, 1996, report entitled ''Protecting the Nation's Blood Supply from Infectious Agents: the Need for New Standards to Meet New Threats,'' the United States House of Representatives Committee on Government Reform and Oversight provided recommendations to FDA on improvement of the biologics regulations. One of the recommendations concerned the need for the development of a more effective system to notify patients when there are adverse events associated with blood products.

In response to this recommendation, FDA, industry, and patient groups have already taken a number of actions to improve the agency's and industry's response to situations related to concerns about the safety of blood products. FDA has improved its procedures for planning, monitoring, coordinating, and directing FDA investigations for a range of situations including error and accident reports, recalls, and reports of injury or illness, including those related to plasma derivatives. Although primary responsibility for notification of recalls falls to the manufacturer of the product being recalled, FDA uses a variety of electronic communications to make information on recalls and withdrawals available to the public. These include information on the Center for Biologics Evaluation and Research World Wide Web home page, a Fax-on-Demand system, press releases, talk papers (FDA briefing documents), and a ''Blood and Plasma Products'' hotline. Interested persons may subscribe electronically to the notification system to receive new information automatically. FDA routinely communicates information regarding recalls and withdrawals of plasma derivatives to consumer groups such as the National Hemophilia Foundation and the Committee of Ten Thousand. FDA continues to work with regulated industry to improve the safety of the blood supply, including the development of new, safer products.

FDA has had extensive dialogue with a variety of interested persons in evaluating the current procedures for identifying and notifying recipients in case of safety issues related to blood products. FDA, along with other Government organizations, held a public workshop on November 19, 1996, to obtain public input on notification of the public on recalls and ongoing investigations (see the notice of meeting in the **Federal Register** of November 1, 1996 (61 FR 56549)). Subsequently, FDA has met with numerous consumer groups and industry organizations to discuss notification issues. After extensive discussions with patient communities and within the Department of Health and Human Services, FDA believes that there is a consensus that persons in custody of a product that may be associated with a potential increased risk of transmitting disease should be so notified; however, it remains unclear as to what specifically would be the most efficient, least burdensome, process that would ensure appropriate notification of all affected persons.

The voluntary programs for notifying recipients in cases of issues related to the quality of blood products are fairly new and efforts continue to recruit participation by patients who are blood product recipients. Thus the success of the voluntary programs cannot yet be fully assessed. However, the success of such voluntary programs will always depend on the continued voluntary support by manufacturers of blood products and the continued vigorous recruitment of patient/recipients to encourage full participation. FDA is concerned that the continued success of patient notification cannot be assured without regulatory standards for the performance of such notification programs and without a clear mechanism of enforcement in the event a notification program is found deficient. FDA intends to continue to monitor progress in the implementation of the voluntary systems and will consider elements of the voluntary systems when developing any regulations resulting from this notice. FDA believes there should be a standardized notification system, clearly understood by industry and by users of blood products, and over which FDA has clear enforcement authority to help ensure that notification consistently and comprehensively takes place.

Accordingly, FDA is considering rulemaking to provide for the prompt notification of patients who may possess certain plasma derivative products for their own use when information indicates a potential for the product to transmit a communicable disease. FDA recognizes that there are several alternatives as to how this notification could best be accomplished. Any such rule would involve the cooperation of a number of entities who must provide information to help ensure that appropriate notification takes place, including the manufacturers of such products, consignees who hold the product for further sale (wholesale distributors), consignees, such as hospitals and pharmacies, who provide the product directly to the patient, and patients. Accordingly, in sections II. and III. of this document FDA outlines the concepts and alternatives it is considering in the development of these

regulations and invites information and comments on the various concepts and alternatives from all interested persons.

II. General Overview of the Regulatory Plan

Under the biologics licensing and quarantine provisions of the Public Health Service Act (42 U.S.C. 262–264) and the drug, device, and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351–353, 355–360, and 371–374)), FDA has the authority to issue regulations designed to protect the public from unsafe or ineffective biological products and to issue regulations necessary to prevent the transmission of communicable diseases. Biological products derived from human plasma have an inherent, potential risk to transmit communicable diseases. Donors of the plasma source material are screened and tested for the potential to transmit a communicable disease. Products made from plasma may be further tested and treated by a process intended to remove or destroy infectious disease agents. However, despite these multiple precautions, there are occasions when problems are identified which may increase the potential risk that the plasma derivative may transmit a communicable disease. Depending on the particular facts, the manufacturer may initiate a recall or market withdrawal of the product so that consignees of the plasma derivative may take appropriate action to prevent the further marketing of the product (see Title 21 of the Code of Federal Regulations (CFR), part 7 (21 CFR part 7) for additional information on the recall and market withdrawal processes).

For some plasma products, generally those that may be chronically administered through the lifetime of the patient, the plasma derivative may be prescribed to the patient and held at the patient's residence until the product is administered. (Note that although FDA is aware only of certain plasma derivative products being routinely held in the patient's custody, FDA intends that any regulations concerning notification would apply to any blood-derived product which may, now or in the future, be released into the custody of a patient.) FDA believes that patients having custody of plasma derivatives are not consistently notified of lot-specific product recalls or withdrawals associated with a potential increased risk of a communicable disease or such notification has not been timely to ensure that appropriate action may be taken by the patient.

There are voluntary tracking and notification systems in place for specific plasma derivatives, but these systems require patients to register with the data base administrator in order for the patients to be notified. In order to protect patients and to better prevent the transmission of communicable diseases through plasma derivatives, FDA is considering the issuance of a proposed rulemaking that would require that patients having custody of plasma derivatives be promptly notified of specific lots associated with a potential increased risk of a communicable disease. Because of the importance of such a notification, FDA is considering defining when notification should take place and setting timeframes during which notification must be performed. The proposed rulemaking would also include requirements for tracking of plasma derivatives to patients who have custody of these products for the purpose of permitting identification of such patients for notifying them of recalls and market withdrawals.

III. Concepts of the Proposed Rulemaking

The following discussion is not intended to indicate the specific content of the proposed rulemaking. It is meant only to describe concepts to be covered by the proposed regulations. The discussion identifies a number of specific topics on which the agency is seeking additional information. However, FDA welcomes comments on any aspect regarding the notification of patients relating to the safety of plasma derivative products. Comments received in response to this advance notice of proposed rulemaking (ANPRM) will be used to develop the proposed rule. FDA specifically requests comments on the concepts that follow.

A. Scope of the Regulations—Types of Blood-Derived Products

The intent of the regulations would be to help ensure that patients possessing plasma derivative products are notified of a potential increased risk of communicable disease so that they may take appropriate action, such as returning the product to the distributing establishment. Therefore, FDA intends to limit the scope of the regulations to those plasma derivatives that may be distributed directly to a patient. Such products include Antihemophilic Factor (AHF or Factor VIII) for the treatment of hemophilia A, Factor IX, used for the treatment of hemophilia B, Alpha-1-Proteinase Inhibitor (Human), used for the treatment of alpha-1 antitrypsin deficiency and products analogous to those listed previously, such as porcine AHF and products made using recombinant technology. The proposed rulemaking would not apply to plasma derivative products, such as albumin, that are not routinely prescribed for home use.

FDA notes that occasionally patients may take custody of Immune Globulin Intravenous (Human) (also known as IGIV) for administration at home. FDA estimates that approximately 5 percent of the IGIV prescribed is taken into the custody of the patient. FDA believes that such patients should be notified in cases when the IGIV is associated with a potential increased risk of transmitting a communicable disease. The agency also recognizes the complexity, expense, and inefficiency of a system which would be needed to track large volumes of product, for the purpose of potentially notifying a small proportion of patients. It may be more efficient to provide specific arrangements for notification at the time the product is prescribed to the limited number of patients who are taking custody of the product for home use. FDA invites comments and recommendations on how appropriate information regarding product safety can be provided to such patients and whether alternative procedures for such a system should be codified as part of the notification rulemaking. FDA also invites comments as to whether other blood products should be included under the regulations, including a discussion of the extent of the increased burdens and public health advantages associated with such an expansion.

Currently, FDA is aware only of plasma derivative products being released into the custody of patients. It is possible that in the future other products, derived from other blood components, such as red blood cells or white blood cells, may be routinely dispensed into the custody of patients. In such a case, FDA intends that the requirements for tracking and notification would also apply to the blood-derived product. Because the information that FDA has so far gathered and the information being sought by FDA pertains primarily to plasma derivative products, this ANPRM will continue to focus upon plasma derivative products. However, FDA invites comments on what additional blood-derived products may be dispensed into the custody of a patient in the future.

As discussed earlier in this document, a number of voluntary efforts are under way to assist in the notification of persons in custody of a plasma derivative product associated with a potential increased risk of transmitting

a communicable disease. Although FDA believes that there may be innate limitations to any voluntary system, little information is available to the agency regarding the effectiveness of the voluntary systems in place. FDA requests data on the effectiveness of such systems in identifying all persons who may have custody of a plasma derivative product and notifying them in case the product is associated with a potential increased risk of transmitting a communicable disease. FDA also requests comments on whether such systems may be improved and, if so, whether regulations establishing a mandatory notification process would remain appropriate.

B. Scope of the Regulations—Reasons for Notification

At this time, FDA intends that the proposed regulations would require notification only for those plasma derivative lots which, within the dating period of the product, may be associated with a potential increased risk of transmitting a communicable disease. In general, FDA believes that notification of end-users should take place in the same instances for which manufacturers are now either recalling or withdrawing plasma derivative products because of a potential increased risk of transmitting disease. A biological product may be unacceptable for human use due to a wide range of reasons, many not related to communicable disease. FDA is inviting comments on how the basis for notification should be defined in the regulations so as to appropriately establish the criteria for determining when notification should be required. FDA is also inviting comments and information on whether the scope should be expanded to cover other instances, which may affect the safety of the product but which may not be associated with a potential increased risk of communicable disease. An established tracking and notification system could be used in the notification of patients having custody of plasma derivatives for all recalls and market withdrawals. FDA invites comments on the adequacy of the current recall process in situations, other than those related to the risk of communicable disease, and the additional benefits that would be provided by requiring patient notification when compared with the additional burdens associated with the notification process.

C. Who Should Be Responsible for Notification and Related Tracking Responsibilities?

In a recall, the manufacturer has primary responsibility for ensuring that the recall is undertaken promptly and that, based on an assessment of the risk, it extends to an appropriate level, such as to the end-user of the product. However, other persons, such as the consignees in receipt of the product, play an integral part in the recall process.

FDA is aware of consumer concerns that manufacturers should not know the identity of a patient using its product. Because of concerns about maintaining confidentiality of patients, FDA believes that the manufacturer should not be required to directly contact patients for notification purposes. Such notification could either be accomplished by those consignees who provided the product to the patient or by an independent third party contracted by the manufacturer to notify patients in the case of a notification or withdrawal related to the potential transmission of a communicable disease, while not divulging patient information to the manufacturer. FDA invites comments as to whether the consignees should be held responsible for notification, whether a manufacturer should be required to contract with a third party to perform notification, or whether either option should be permitted under the regulations.

D. Tracking of the Consignment of Applicable Plasma Derivatives

FDA intends that the proposed rule would require that plasma derivatives prescribed to patients for home use be tracked from the manufacturer, to any consignees, and ultimately to such patients for the purpose of permitting identification of such patients when they need to be notified about a product associated with the potential increased risk of transmitting a communicable disease. The tracking of product to intermediate consignees would be necessary for notifying them about the product risk and thus preventing further distribution of the implicated product lot to patients for home use. Depending on the mechanism of notification (see section III.G of this document), required tracking information could be specific for each lot or could simply be the ability to identify all consignees and patients who have received that specific plasma derivative product, regardless of what product lots they may have received. FDA invites comments, data, and other information on the potential recordkeeping burdens that would be associated with tracking such plasma derivative products, including any estimates of the time it would take to prepare such records and of the number of recordkeeping entries that would be necessary each year to maintain these tracking records. Data are requested both for keeping lot specific tracking information and for product specific information.

E. Initiation of Notification

In most cases the manufacturer would be the first to determine that a plasma derivative may be associated with a potential increased risk of transmitting a communicable disease. However, based, for example, on consumer complaints, laboratory evidence, or information obtained during inspection by FDA or from other public health agencies, FDA anticipates there would be occasions when it is FDA that makes the initial determination that notification is required. In such cases, FDA believes the most efficient means of initiating notification would be for FDA to inform the manufacturer by an appropriate means of rapid communication, such as fax, electronic mail, or telephone, to initiate notification, immediately followed by written information further documenting why the agency deems notification necessary. The previous description is a simplification of the process which would generally take place when problems are perceived with a product. In most cases, there would be considerable discussion among experts, at FDA and at the manufacturer, to evaluate the available information and assess its implications for the safety of the affected products before a decision to notify would be made. Thus, the process described previously would only be the final step in the determination that notification is required.

FDA requests comments on what should be the required elements of the determination that mandatory notification is to take place and what information regarding that determination should be shared between FDA and the manufacturer.

F. Timing for Notification

Because the plasma derivatives held by a patient may be administered at any time, FDA believes that notification of the patient should take place as rapidly as possible after the determination that a notification is necessary. In some cases the first attempt at notifying a patient may not be fruitful; the patient may be away from his or her home or otherwise unavailable. Accordingly, FDA is also considering a regulatory standard for the time by which full notification of patients should be completed (or by when it is determined that the patient cannot be notified with the currently available information). From the time that either the

manufacturer determines notification is appropriate or FDA informs the manufacturer that notification is required, FDA is considering a standard that the initial attempt to notify all persons with custody of the product must take place within 2 days. For those cases when the initial notification attempt fails, FDA is considering requirements that procedures must be in place for two additional attempts for notification; with the final attempt in written form taking place within 1 week from the beginning of the notification process. FDA invites comments and information on how rapidly it is feasible to attempt to contact patients who may possess the product subject to notification and how much time should be allotted to complete the notification process. If possible, the comments should describe in detail the steps which should take place in the notification process and the time which should be allotted for each step. FDA also invites comments on how much time should be permitted to contact consignees, other than the patients with custody of the product, who also may be in possession of the product.

G. Who Should Be Notified

FDA's public health objectives would be met if only those patients are notified who possess the product lot(s) with an increased potential for transmitting a communicable disease. However, a possible alternative would be to notify all patients who have been dispensed the brand of plasma derivative in question during the time period that the product lot subject to the notification has been in distribution. This method would negate the need to track plasma derivative products to the end-user by lot number. FDA invites comments on the comparative advantages and disadvantages of notifying only those patients who may possess the product lot in question versus notifying all patients who may possess the indicated brand of the plasma derivative. Under any system, the information provided to patients would be lot specific.

H. Information Included in a Notification of Patients

Required information to include in a notification of patients could include specific lot information, a statement to describe the risk potentially affecting the product lot, and instructions for further action to be taken by the patients who have custody of the product lot in question. FDA invites comments on whether the previous information is appropriate and adequately comprehensive for notification.

I. Adequacy of the Notification Process; Quality Assurance

FDA recognizes that, even with a standard mandatory process, notification of every patient may not be successful. For example, the patient may have moved or may be away from his or her home for an extended period of time. FDA is considering a requirement that the manufacturer have a process in place to evaluate, in cooperation with its consignees or any third party involved in notification, the effectiveness of its notification process, such as through the selected sampling of patients who should have been notified, and, with such information, determine how its notification process could be improved. FDA invites comments on the most appropriate means for evaluating the effectiveness of the notification process and who (the manufacturer, consignees, a third party) should be involved in such an evaluation.

J. Relationship of Notification With Product Recalls and Withdrawals

In most, if not all, situations for which FDA is considering requiring notification, manufacturers, under current procedures, would subject the product to recall or market withdrawal. Procedures for product recalls are presented as guidance in 21 CFR part 7. ''Market withdrawal'' is defined in § 7.3. Product recalls and market withdrawals are similar functions for the removal or correction of a marketed product. In the case of recalls the product is considered to be in violation of the law and may be subject to a regulatory action by FDA, such as seizure of the product. A market withdrawal may be performed for a distributed product associated with a minor violation or for products that are not in violation of the law. Many of the procedures described in this ANPRM as potentially appropriate for the notification process are identical or similar to procedures generally performed in a product recall or market withdrawal (see, for example, the procedures for development of a recall strategy (§ 7.42(a)(1)), conducting effectiveness checks (§ 7.42(b)(3)), and recall communications (§ 7.49)). FDA invites comments on the interrelationship among product recalls, withdrawals, and the notification process described in this ANPRM. What recall/withdrawal procedures would continue to be appropriate in the event FDA requires patient notification? How may the process best be integrated to ensure effective notification and product removal?

K. Informing Patients of the Notification Process

FDA believes that a patient taking custody of a plasma derivative should be informed that she or he will be notified in the event the plasma derivative is associated with a potential increased risk of transmitting a communicable disease. This information should be provided, in writing, when receiving delivery of the plasma product or before, such as at the time the product is prescribed. FDA invites comments on whether such information can best be provided in the form of patient labeling accompanying the product or should be delivered by other means. FDA also invites comments on whether such information can be standardized for all plasma derivative products and, if so, who should be responsible for preparing such information.

IV. Request for Comments

Interested persons may, on or before November 17, 1999, submit to the Dockets Management Branch (address above) written comments regarding the general and specific issues presented in this ANPRM. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This ANPRM is issued under section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*) and under authority of the Commissioner of Food and Drugs.

Dated: June 15, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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Part V

Department of Transportation

Research and Special Programs Administration

49 CFR Parts 171, 172 and 175

Hazardous Materials: Chemical Oxidizers and Compressed Oxygen Aboard Aircraft; Final Rule

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 171, 172, and 175

[Docket No. HM–224A]

RIN 2137–AC92

Hazardous Materials: Chemical Oxidizers and Compressed Oxygen Aboard Aircraft

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Final rule.

SUMMARY: RSPA is amending the Hazardous Materials Regulations to: Prohibit the carriage of chemical oxidizers in inaccessible aircraft cargo compartments that do not have a fire or smoke detection and fire suppression system; require oxygen cylinders to be placed in an outer packaging when transported aboard aircraft; limit the number of oxygen cylinders that may be stowed on an aircraft in inaccessible cargo compartments that do not have a fire or smoke detection system and a fire suppression system (e.g., a Class D cargo compartment); limit the number of oxygen cylinders that may be stowed in a Class B cargo compartment or its equivalent (i.e., an accessible cargo compartment equipped with a fire or smoke detection system but not a fire suppression system); authorize transportation of a limited number of oxygen cylinders in the passenger cabin of passenger-carrying aircraft; and prohibit the carriage of personal-use chemical oxygen generators on passenger-carrying aircraft and the carriage of spent chemical oxygen generators on both passenger-carrying and cargo aircraft.

This final rule is being issued in consultation with the Federal Aviation Administration (FAA) to enhance air transportation safety.

DATES: *Effective Date:* The effective date of these amendments is March 1, 2000.

Permissive Compliance Date: Compliance with the requirements adopted herein is authorized as of October 22, 1999.

Incorporation by Reference Date: The incorporation by reference of a publication listed in this final rule is approved by the Director of the Federal Register as of March 1, 2000.

FOR FURTHER INFORMATION CONTACT: Diane LaValle or John Gale, Office of Hazardous Materials Standards, (202) 366–8553, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street S.W., Washington DC 20590–0001.

SUPPLEMENTARY INFORMATION:

I. Background

On May 11, 1996, ValuJet Airlines flight No. 596 crashed in the Florida Everglades resulting in 110 fatalities. The National Transportation Safety Board (NTSB) found that chemical oxygen generators initiated and then intensified a fire in a Class D cargo compartment, which caused the crash. Shortly after the crash, NTSB recommended that RSPA, together with FAA, ''prohibit the transportation of oxidizers and oxidizing materials (e.g., nitric acid) in cargo compartments that do not have fire or smoke detection systems.''

In subsequent rulemaking actions, RSPA has prohibited the transportation of chemical oxygen generators as cargo on board passenger-carrying airlines, and issued standards governing the transportation of chemical oxygen generators on cargo-only aircraft. 61 FR 26418 (May 24, 1996); 61 FR 68952 (Dec. 30, 1996); 62 FR 30767 (June 5, 1997); 62 FR 34667 (June 27, 1997). On February 17, 1998, FAA published a final rule that upgraded the fire safety standards for Class D compartments for certain transport-category airplanes. 63 FR 8033. FAA's rulemaking has a compliance date of March 19, 2001.

On December 30, 1996, RSPA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (61 FR 68955) proposing to amend the Hazardous Materials Regulations (HMR; 49 CFR Parts 171–180) to prohibit the carriage of oxidizers, including compressed oxygen, in passenger-carrying aircraft. That proposal also would have had the effect of limiting packages of oxidizers that are allowed on cargo aircraft to locations accessible to crew members (see 49 CFR 175.85(b)). In the December 30, 1996 NPRM, RSPA analyzed the possible prohibition of oxidizers in Class D cargo compartments only, and proposed a new § 175.85(d) to prohibit loading or transporting in a Class D compartment any package containing a hazardous material for which an OXIDIZER or OXYGEN label is required. On August 20, 1997, RSPA published a supplemental notice of proposed rulemaking (SNPRM) (62 FR 44374) further analyzing the possible prohibition of oxidizers aboard passenger-carrying aircraft in Class B and C cargo compartments.

The classification of cargo compartments aboard transport-category aircraft is specified in 14 CFR 25.857 and discussed in RSPA's NPRM and SNPRM. In general, a Class B compartment is one which is accessible to a crew member with a hand-held fire extinguisher and has an approved smoke or fire detection system. Class C and D compartments are not accessible during flight and have means to control ventilation and exclude hazardous quantities of smoke or flames from the passenger compartment and cockpit. A Class C compartment also has an approved smoke or fire detection system and a built-in fire suppression system. In this final rule, when reference is made to Class B, Class C or Class D aircraft cargo compartments, we are also including cargo compartments on non-transport category airplanes that have similar characteristics. The limitations and prohibitions for Class D compartments also apply to non-transport category airplanes that do not have detection and suppression equipment, similar to Class D compartments in transport-category airplanes.

In the NPRM and SNPRM, RSPA also proposed to completely prohibit the transportation of chemical oxygen generators that have been discharged (''spent'') and to prohibit the transportation of personal-use chemical oxygen generators on passenger-carrying aircraft. On August 27, 1998, FAA published an NPRM proposing to ban, in certain domestic operations, the transportation of devices designed to chemically generate oxygen, including devices that have not yet been charged for the generation of oxygen. 63 FR 45913. In response to a request from nine industry associations, on January 14, 1998, RSPA and FAA held a public meeting to more fully explore all the issues relating to the proposals in the NPRM and SNPRM.

The amendments adopted in this final rule respond to the NTSB recommendation and are based on the merits of comments and the assessment of RSPA and the FAA of the hazards posed by oxidizers. In its recommendation, NTSB cited three previous incidents in which oxidizers caused fires aboard aircraft. In each of these incidents, there were apparent or known serious violations of the HMR. RSPA and FAA are not aware of any fire aboard an aircraft having been caused directly by transport of oxidizers in conformance with the HMR. However, RSPA and FAA agree with the NTSB that, in certain circumstances, oxidizers can contribute to the severity of a fire and pose an unreasonable risk when transported in an inaccessible cargo compartment which does not have a fire or smoke detection system and a fire suppression system.

II. Comments and Regulatory Changes

A. General

RSPA received more than 55 written comments, and 14 persons made oral presentations at the public meeting, in response to the NPRM and SNPRM. The commenters included shippers and carriers of oxidizers by air, related trade associations, the NTSB, and persons who need supplemental oxygen during flight for medical reasons. In general, the persons that submitted comments:

(1) Supported the prohibition of oxidizers, other than oxygen, in those cargo compartments that do not have fire or smoke detection and fire suppression systems;

(2) Disagreed with the proposed total prohibition of oxidizers carried in cargo compartments aboard passenger-carrying aircraft and in inaccessible cargo compartments aboard cargo aircraft, including those compartments with detection and suppression systems;

(3) Disagreed with the proposed prohibition of the carriage of compressed oxygen in cargo compartments aboard passenger-carrying aircraft; and

(4) Supported the proposals to prohibit the transportation of spent oxygen generators aboard aircraft and to eliminate the exception provided in 49 CFR 175.10(a)(24) for personal oxygen generators.

B. Oxidizers

1. Summary of Comments on Chemical Oxidizers

RSPA proposed to prohibit the transportation of chemical oxidizers aboard passenger-carrying aircraft and in inaccessible cargo compartments of cargo aircraft. Most of the commenters agreed with the proposal to prohibit chemical oxidizers in cargo compartments that are not equipped with fire or smoke detection systems and fire suppression systems, but disagreed with the proposal to ban oxidizers from cargo compartments with fire or smoke detection and fire suppression systems.

Air Products and Chemicals, Inc. supported the rule as proposed. It stated that ''the prohibition of oxidizers and similar materials aboard passenger-carrying aircraft is a sensible approach to improving the safety of passenger flights.'' NTSB stated that it ''supports prohibiting the carriage of oxidizers, including compressed oxygen, in Class D compartments because these compartments do not have smoke and fire detection systems * * *'' In its comments to the SNPRM, NTSB referred to an earlier recommendation that FAA ''consider the effects of authorized hazardous materials cargo in fires for all types of cargo compartments.'' It urged RSPA and FAA to complete a study of the risks associated with the transportation of hazardous materials on aircraft and ''to ban any hazardous materials, including oxidizers, that cannot be safely transported in aircraft cargo compartments.''

Several commenters specifically stated that they did not support the ban of an entire division of hazardous materials aboard passenger-carrying aircraft and that a complete ban of oxidizers would increase the number of undeclared hazardous materials. The Airline Pilots Association (ALPA) stated ''prohibiting the carriage of *all* oxidizers may introduce additional hazards. This may inadvertently force shippers into illegally shipping materials as undeclared * * *'' ALPA went on to say that ''the complete banning of all oxidizers * * * goes beyond the seemingly obvious safety implication and does not appear to be reasonable.''

Many other commenters noted that, to date, incidents involving hazardous materials have been due to lack of compliance with the HMR. They stated that the better course of action would be to increase education and enforcement, rather than ban an entire category of hazardous materials. The Conference on Safe Transportation of Hazardous Articles stated:

> People who ship undeclared hazardous materials do not read the CFRs. You can give all the instructions you like in the regulations, and the people who ignored the instructions in the past will ignore them in the future. Now, in fact, the prohibition will give them greater incentive to embrace ignorance.

The Hazardous Materials Advisory Council (HMAC) stated its belief that:

> * * * the rule's provisions will do nothing to address the known problem of undeclared or misdeclared shipments of hazardous materials and may be counterproductive by increasing such shipments by unscrupulous persons. In our opinion this could present a more dangerous situation to passengers and airline employees than at present.

Several commenters stated that a ban of certain materials on aircraft is no guarantee that those who are unaware of the regulations will not continue to ship undeclared hazardous materials. They suggested that public education and aggressive enforcement (including appropriate penalties for violation of the HMR) would better promote safe transportation. Mallinckrodt, a shipper of oxidizers, stated, ''We ship oxidizers, paying particular attention to complying with these methods and have had no incidents of which we are aware. We do not feel that we should be penalized for incidents as outlined in the Docket, which were clear violations of the law.''

Hach Company manufactures and distributes several hundred products that are or contain oxidizing materials, including laboratory instruments, process analyzers, test kits and analytical reagents some of which are used to analyze the quality and safety of water. It ships the majority of its international orders by air, primarily on passenger-carrying aircraft. Hach stated that it would prefer to ship by cargo aircraft but that cargo aircraft are not available to a large percentage of the end-user locations. It also stated that ocean transportation is not a viable alternative because of location, time and cost constraints. Hach stated that the proposed rule, if promulgated could put it at a significant commercial disadvantage with its foreign competitors. Hach supported a prohibition on transportation of oxidizers in Class D cargo compartments, but opposed a prohibition that would apply to other cargo compartments.

The International Air Transport Association (IATA) stated that cargo aircraft are not a substitute for passenger-carrying aircraft because cargo operations serve only a fraction of airports, international and domestic, and do not have the frequency of service required by shippers. IATA stated ''Typically, a dangerous goods shipment by air is time critical and the facility provided by passenger aircraft service is essential to shipper's requirements.'' Another commenter stated that the safety need for the proposed general prohibition on the transport of all oxidizers aboard passenger-carrying aircraft has not been technically or rationally proven by FAA and RSPA.

Some commenters expressed concern that RSPA and FAA would ban all materials within Division 5.1 from passenger-carrying aircraft without regard to the lesser hazards posed by materials in lower packing groups, or shipped in limited quantities. ATA stated that the proposed rules:

> * * * offer no analysis or rationale to explain how a properly packaged, low-oxidizing potential material would pose such risks. In this regard, the transport, for example, of properly packaged and identified low-oxidizing potential (i.e., Packing Group III) solid oxidizers, is not considered to pose a significant risk to safety in air transport. Such a material would be incapable of spontaneously initiating a fire (even when in contact with organic material) under conditions normally incident to transport.

ATA also stated that ''normal'' oxidizers can only reasonably be

envisioned contributing to a fire originating in adjacent cargo when the fire has progressed to the extent that a packaging containing ''normal'' oxidizers has been substantially degraded. In such a case, ATA stated the fire may be uncontrollable in any event or the contribution to the intensity of the fire of a low-oxidizing potential solid oxidizer may be insignificant. ALPA suggested that RSPA further examine those oxidizing substances presently authorized by the HMR to be carried aboard passenger-carrying aircraft which pose the greatest potential risk to safety and those oxidizers that have caused problems when transported by air. ALPA suggested that, following this re-examination, RSPA should determine whether changes to the current HMR might be necessary concerning these materials, such as decreasing net quantity limitations, increasing the packaging requirements, or prohibiting their carriage by aircraft.

2. Summary of Comments on Compressed Oxygen

RSPA proposed to prohibit the transportation of compressed oxygen as cargo aboard passenger-carrying aircraft, and in inaccessible locations aboard cargo aircraft. RSPA also proposed, based on the provision of an existing exemption, to allow a limited number of airline-owned and passenger-owned oxygen cylinders to be stowed in the cabin of a passenger-carrying aircraft when placed in an overpack. RSPA also proposed to require that the overpack be labeled CARGO AIRCRAFT ONLY but marked with the statement ''Passenger cabin acceptable per 49 CFR 175.10.''

As already mentioned NTSB supported the proposal to prohibit the carriage of compressed oxygen in Class D compartments. Air Products and Chemicals, Inc. also supported the proposal and stated, ''the result of the proposal should improve overall aircraft safety, but, there should also be an effort to improve enforcement of all rules pertaining to hazardous and forbidden materials in airplanes.''

The majority of the commenters opposed the proposal. Most commenters stated that transporting oxygen cylinders in the cargo hold does not present a significant risk. For example, the Regional Airline Association (RAA) stated ''RSPA has failed to show that the transportation of pressurized oxygen is sufficiently hazardous to deny shipment within Class C and Class D compartments.'' RAA went on to say that airlines that operate in remote locations where ground transportation is not available, such as Alaska, will have to either withdraw from operations or fly to their destination knowing that their destination is not equipped to return them to service if they deplete an oxygen bottle during the flight.

The Alaska Air Carriers Association (AACA) and Peninsula Airways also opposed the proposed rule, particularly regarding oxygen, due to the adverse consequence on transportation in and through Alaska. Peninsula Airways stated ''implementation of the NPRM's provisions that affect this issue will make it virtually impossible to legally provide medical oxygen for passengers/patients in remote areas of Alaska.'' Peninsula Airways and AACA both pointed out that Section 1205 of Public Law 104–264, Regulations Affecting Intrastate Aviation in Alaska, give FAA the authority to consider Alaska's unique transportation circumstances when conducting rulemaking. Peninsula Airways stated that ''this is clearly a situation where RSPA must reconsider the NPRM's impact on Alaska and modify the proposed rule * * * to make it workable, safe to use and safe to transport medical oxygen cylinders in Alaska.''

Commenters also contended that prohibiting transportation of compressed oxygen on board passenger-carrying aircraft would have significant cost impacts on the airline industry and severely hamper the ability of disabled persons to travel by the air mode. ATA stated that a fire capable of generating enough heat to potentially affect an oxygen cylinder would cause severe structural damage to the aircraft before the cylinder would ever be dangerously involved.

Caledonia Airways disagreed with the proposed exception for transporting compressed oxygen in the passenger cabin. It stated that such transportation is contrary to any training that airline personnel have received and also conflicts with the International Civil Aviation Organization's (ICAO) Technical Instructions for the Safe Transportation of Dangerous Goods. Other commenters noted that adoption of the proposed ban on compressed oxygen, in conjunction with the general ban on carriage of dangerous goods in the passenger cabin set forth in the ICAO Technical Instructions, could effectively prohibit any transportation of oxygen cylinders as COMAT (airline company material) on international flights. Commenters also stated that limiting a carrier to six COMAT cylinders per flight would unnecessarily restrict its ability to pre-position cylinders and to transport cylinders to locations where they are needed to replace used cylinders.

RAA stated that the proposed exception for oxygen cylinders in the cabin is a suitable alternative for transportation of medical oxygen cylinders, but it does not address the needs of regional operators to ship spare oxygen cylinders used in support of aircraft pressurized oxygen systems. ALPA stated that many airplanes do not have available storage locations of adequate size and strength to hold oxygen cylinders contained within their strong outer packagings. ALPA went on to say that for such aircraft, creation of such areas or compartments would require significant investment in engineering development and aircraft retrofitting. Qantas Airlines pointed out that an oxygen cylinder is often an unwieldy and heavy piece of equipment which represents a serious hazard to passengers in the cabin not only in regular handling, but especially during turbulence and other in-flight emergencies.

ALPA specifically disagreed with the statement in the NPRM that it would be safer to carry personal medical oxygen cylinders in the passenger cabin because the crew could quickly remove the cylinders from any fire area of the cabin. It stated that the aircraft crew should not be considered a fire suppression resource. In its view, a member of flight deck crew on a two-person crew would not leave his or her station and enter a compartment that is on fire to attempt to fight the fire, nor move a package containing an oxidizer away from the fire.

Many commenters noted that there has not been any incident involving the transport of compressed oxygen in cylinders designed for and used aboard aircraft in any compartment, including an inaccessible cargo compartment. IATA pointed out that there is no record of any lives having been lost due to properly packaged oxidizers, including oxygen, in the 76 years of commercial aviation history and, in particular, since the implementation of the first air-mode Dangerous Goods Code in 1956. ATA stated that the industry system of COMAT distribution of oxygen cylinders has been safely in place since supplemental oxygen was needed on commercial aircraft between 1946–1948 when the Lockheed Constellation, Douglas DC–6 and Convair aircraft entered service. Air New Zealand, pointing out that there are large quantities of oxygen stored in cylinders behind the sidewalls of cargo compartments, stated that the only protection these cylinders have from a cargo compartment fire is the compartment wall lining which meets the flame penetration requirements of

14 CFR 25.855. Air New Zealand went on to say that ''it would be logical to ship cylinders in the cargo compartment in overpacks meeting the same flame penetration standards.''

Most of the comments opposing the proposals related to the transportation of compressed oxygen aboard passenger-carrying aircraft were from airlines who need to resupply (or deploy) charged oxygen cylinders for compliance with FAA airworthiness requirements and for use by passengers who require supplemental oxygen during flight. Several airlines stated that they store the oxygen cylinders at their hub facilities where they can safeguard their storage and maintenance and then deploy them as needed aboard their aircraft to other operating locations. ALPA pointed out that without the required oxygen for crew and passengers, an aircraft is not considered airworthy and is not authorized to be flown. It stated that one way to restore the aircraft to a flyable status is to remove and replace oxygen cylinders, and the potential for an aircraft being grounded at a non-maintenance station is great if these fully charged cylinders may not be moved by an airline around its system.

Carnival Air Lines stated that it would be forced to rely on other carriers to resupply its cylinders and position its maintenance and replacement parts. Carnival also stated that this forced reliance upon other carriers would inevitably lead to at least occasional cancellations or lengthy flight delays resulting from an aircraft being forced out of service awaiting required oxygen. It stated that the costs associated with these delays would be ''very substantial.''

Several airline commenters stated that if the amendments were adopted as proposed they will be unable to provide the current level of service without incurring significant costs. For example, Continental Airlines stated that it transports approximately 300 oxygen cylinders per month and if the proposal is adopted it would not be able to effectively and efficiently distribute medical oxygen to the places where and when it is needed in order to accommodate passenger needs.

Numerous commenters were concerned about the proposed placement of the Cargo Aircraft Only (CAO) (49 CFR 172.448) label on cylinders of oxygen that would be transported in the cabin of a passenger-carrying aircraft. Some stated that adoption of this proposal would cause unacceptable confusion and would be detrimental to safety. Others stated that allowing one material labeled CAO to be loaded in a passenger-carrying aircraft would dilute the meaning of the label and cause confusion. ALPA stated that placing packages of hazardous materials that are labeled CAO in passenger-carrying aircraft is ''totally unacceptable and will not be tolerated.'' ALPA also stated that if a label must be used, then development of a separate ''accessible while inflight'' label may be warranted. ATA stated that ''misuse'' of the hazard communication system would cause confusion about the true meaning of the Cargo Aircraft Only label, which may well increase the potential for a serious incident involving a passenger-carrying aircraft.

The National Association for Medical Direction of Respiratory Care (NAMDRC) and the American Lung Association (ALA) supported the proposal to allow the carriage of passenger-owned cylinders of compressed oxygen in the cabin of the aircraft. NAMDRC and ALA also stated that this exception would provide patients timely access to their personal oxygen containers upon landing at a layover site or at their final destination. These commenters, however, were under the mistaken impression that this exception would allow passengers to transport their cylinders in the aircraft by relinquishing the cylinders to the flight crew. These commenters also asked: (1) Will the airlines have an option or will they be required to transport the oxygen cylinders? (2) Will the airlines be able to charge for the service? (3) What documentation or security measures will be required for transport of the oxygen cylinders? and (4) What types of oxygen cylinders will be allowed to be stowed in the cabin and what type of testing will be required before a cylinder is allowed on the aircraft?

3. RSPA Response to Comments

i. Chemical Oxidizers. Oxidizers currently authorized for carriage aboard passenger aircraft in inaccessible cargo compartments will not spontaneously initiate a fire. The potential hazard posed by these oxidizers is that, if a fire were to occur elsewhere in the compartment, such as in luggage or other cargo, and if there were no means to suppress or extinguish the fire, the fire might burn long enough to involve the oxidizer. The oxidizer, even in Packing Group III, could potentially provide an oxygen source which could intensify the fire to an extent that the limited safety features of the compartment would be ineffective. For these reasons, and based on its review of comments received to the NPRM, SNPRM and at the public hearing, RSPA believes that there is a need to prohibit the transportation of chemical oxidizers (i.e., oxidizers other than compressed oxygen) in inaccessible cargo compartments that do not have fire or smoke detection and fire suppression systems. Therefore, consistent with the NTSB recommendation, RSPA is prohibiting the transportation of chemical oxidizers in inaccessible cargo compartments that do not have fire or smoke detection and fire suppression systems.

Based on evaluation of comments and the hazards posed by chemical oxidizers, RSPA does not believe that chemical oxidizers should be completely forbidden aboard passenger-carrying aircraft. RSPA is confident that chemical oxidizers can be safely transported in Class B, and Class C compartments when transported in accordance with the HMR. RSPA is also confident that the safety features of a Class B compartment (i.e., an accessible compartment with fire or smoke detection equipment) and those of a Class C compartment (i.e., an inaccessible cargo compartment that has both a fire or smoke detection system and a fire suppression system) counter the risk posed to an aircraft from the carriage of chemical oxidizers that are transported in accordance with the HMR. Therefore, RSPA is not adopting the proposal to prohibit the carriage of chemical oxidizers aboard passenger-carrying aircraft in Class B or Class C aircraft cargo compartments.

ii. Compressed Oxygen. The potential hazard posed by compressed oxygen is that it will intensify a fire. Thus, if a fire, from any source, were to occur in an aircraft cargo compartment containing an oxygen cylinder, the fire might burn long enough to heat the cylinder sufficiently to cause the pressure relief mechanism on the cylinder to open. The released oxygen could then intensify the fire to an extent that the safety features of the compartment would be ineffective, potentially resulting in the loss of the aircraft.

Under the HMR, compressed oxygen must be packaged in a DOT specification cylinder, constructed of steel or aluminum. The cylinder is required to incorporate a pressure relief device that will release its contents if the internal pressure in the cylinder approaches the test pressure of the cylinder. If the cylinder incorporates a valve, sufficient protection must be provided to prevent operation of, and damage to the valve during transportation, such as by boxing or crating the cylinder or by equipping it with protective caps or head rings (see 49 CFR 173.27(g)). Some types of

cylinders may only be shipped in strong outside packagings, regardless of whether or not the cylinder incorporates a valve (see 49 CFR 173.301(k)). An overpack or outer packaging commonly used by the airlines to transport their oxygen cylinders is the ATA Specification No. 300, Packaging of Airline Supplies, Category I. An ATA Specification No. 300 Category I (ATA 300) overpack or outer packaging is a resilient, durable overpack intended to be reused for a minimum of 100 round trips which meets specified performance standards, as demonstrated by design tests (e.g., drop test and puncture resistance). The overpack or outer packaging must also provide protection from shock and vibration.

Numerous commenters pointed out the long safety record that oxygen cylinders have had in commercial aviation and expressed the view that RSPA and FAA had no basis for proposing to prohibit the transportation of oxygen cylinders aboard passenger-carrying aircraft. Commenters requested that RSPA and FAA reevaluate the proposal regarding oxygen cylinders. After the ValuJet accident, RSPA and FAA began evaluating the risks associated with the transport of hazardous materials by aircraft. This rule reflects the agency's decisions regarding oxidizers and compressed oxygen cylinders and is based on written comments, information from the public hearing and FAA testing.

At the public hearing, the FAA asked whether any of the attendees were aware of any testing results that would support assertions by some commenters that a fire capable of generating enough heat to potentially affect an oxygen cylinder would cause severe structural damage to the aircraft before the cylinder would ever be dangerously involved. No one cited any tests. In an effort to establish whether these assertions were valid, the FAA conducted oven, fire, and overpack tests on compressed oxygen cylinders. These tests were conducted at the FAA Technical Center. A copy of the test report is available for review in the public docket. As discussed below, the FAA found that oxygen cylinders release their contents at temperatures well-below those that would be needed to damage aircraft cargo compartment liners and structures. However, an outer packaging or overpack will lengthen the time for a cylinder to release its contents at these temperatures.

Oven Test

The purpose of the first test series was to determine the approximate time and rate of release when an unprotected cylinder is exposed to high temperatures, as might be experienced in a cargo compartment fire. For this test, cylinders normally used for compressed oxygen were filled with nitrogen to 1,800 p.s.i. This test was performed on three cylinders of different capacity (i.e., 11, 76.5 and 115 cubic foot capacity). Each cylinder was placed in an industrial-type electric conduction oven and the temperature of the oven was increased to 400°F. On average, the cylinders released their contents within 14 minutes, when the temperature inside the oven was approximately 370°F. The average external temperature of the cylinder at the time of release was 300°F.

Fire Tests

During the second test series, FAA attempted to determine the effect of releasing oxygen during a fire. For this test, an empty cylinder was placed in a steel frame receptacle constructed in the shape of a LD–3 container which is typically used in the lower deck of a wide-body aircraft. Cardboard boxes filled with shredded paper were loaded into the LD–3 container and a small fire initiated. When the temperature of the cylinder reached the temperature obtained during the first (oven) test, the oxygen was vented into the container through piping. This test was performed three times using the contents of an 11 cubic foot cylinder and once using about 22 cubic feet of oxygen. The first time a slight increase in temperature in the LD–3 container was observed, but the oxygen release had little overall impact on the fire. The second time the smoldering fire erupted violently with visible flames appearing at one edge of the container. Although violent, the eruption was short in duration and the fire was contained. The third time the release of oxygen again caused a violent reaction inside the container, which produced enough pressure to force open taped seams on the container. However, it was again very short in duration much like the previous test. The fourth time, the temperature in the LD–3 container increased dramatically immediately following the oxygen release and the fire completely burned through the ceiling and part of the front side of the container, totally destroying it.

Overpack Tests

During the third test series the level of thermal protection provided by a variety of overpack or outer packagings was examined. First, currently available overpack or outer packagings meeting ATA 300, Category I and containing a 76.5 cubic foot cylinder filled with nitrogen were placed in an oven and the temperature was increased to 400 °F. This test was repeated numerous times. The first time, after sixty minutes, the cylinder's surface temperature ranged from 230 °F to 280 °F, below the temperature at which the pressure relief mechanism usually actuates to relieve the pressure within the cylinder. The test was terminated after 69 minutes with the maximum surface temperature of the cylinder reaching 300 °F. The second time, after 60 minutes the surface temperature of the cylinder reached 300 °F (the temperature at which the pressure relief mechanism usually actuates). The third time the surface temperature of the cylinder reached 300 °F after 90 minutes, at which time the test was terminated.

Then, in an effort to evaluate the increase in thermal protection offered by a modified overpack case, additional tests were performed on overpacks specifically designed for this purpose and having an exterior made of a flame retardant thermoplastic known as Kydex. In addition, a one inch thick fiberglass insulation was sandwiched between the exterior layer of Kydex and an inner layer of foamed plastic. The test was allowed to progress for approximately 60 minutes without the cylinder surface temperature exceeding 100 °F.

As demonstrated by these tests, when the surface temperature of a cylinder of compressed oxygen reaches approximately 300 °F, the increase in pressure causes the cylinder's pressure relief mechanism to open and release oxygen. If oxygen vents directly into the fire it could cause a potentially catastrophic event. However, these tests also show that an outer packaging that provides greater flame penetration resistance and thermal protection can increase the level of safety in the transportation of compressed oxygen aboard aircraft. Some thermal protection, up to 60 minutes or more, is provided by overpacks or outer packagings meeting the ATA 300 specification. Even more protection would be provided by an improved overpack that provides thermal protection and satisfies flame protection criteria.

The tests performed by FAA demonstrate that there is an increased risk posed by the presence of compressed oxygen in the event of a fire in a cargo compartment. This risk is due to the fact that, if the temperature of an oxygen cylinder reaches approximately 300 °F, the cylinder will vent oxygen into the cargo compartment and intensify the fire. Consequently, action can and should be taken to reduce or eliminate this risk. At this time, RSPA

does not believe that a complete prohibition on the transportation of oxygen cylinders aboard passenger-carrying aircraft will be necessary. Thus, RSPA is permitting oxygen cylinders to be loaded into and transported on passenger-carrying aircraft and in inaccessible locations on cargo-only aircraft subject to restrictions. Furthermore, RSPA and FAA are developing additional standards for protection of oxygen cylinders to be proposed in a separate future rulemaking. RSPA is not adopting the proposal to require the ''Cargo Aircraft Only'' label on cylinders of compressed oxygen because it is continuing to allow compressed oxygen to be carried in cargo compartments of passenger aircraft.

Based on the merits of comments, past shipping experience, FAA testing and its own evaluation, in this final rule, RSPA is amending requirements for the packaging, stowage and transport of oxygen cylinders on aircraft, summarized as follows:

- For transportation aboard a passenger-carrying aircraft or in an inaccessible cargo location on a cargo-only aircraft, each cylinder must be placed in an overpack or an outer packaging that satisfies the performance criteria in ATA Specification 300.
- Each cylinder must be stowed horizontally on or as close as practicable to the floor of the cargo compartment or unit load device.
- No more than a total of six cylinders may be stowed on an aircraft in inaccessible cargo compartments that do not have a fire or smoke detection system and a fire suppression system (e.g., a Class D cargo compartment).
- No more than six cylinders may be stowed in a Class B cargo compartment or its equivalent (i.e., an accessible cargo compartment equipped with a fire or smoke detection system but not a fire suppression system), except that one additional cylinder containing medical-use oxygen may be carried per passenger needing the oxygen at destination.
- A limited number of oxygen cylinders, each with a capacity no greater than 850 liters (30 cubic feet), may be carried in the passenger cabin of a passenger-carrying aircraft. This authorization is limited to no more than six airline-owned cylinders and one additional cylinder containing medical-use oxygen per passenger needing the oxygen at destination.

For transportation aboard a passenger-carrying aircraft or in an inaccessible cargo location on a cargo-only aircraft, RSPA is requiring that each cylinder of compressed oxygen be placed in an overpack or outer packaging meeting the performance criteria in ATA Specification 300. (See Special Provision A52 in the amendment to Section 172.102 of this final rule.) RSPA believes requiring cylinders of compressed oxygen to be placed in these overpacks or outer packagings provides an incremental level of safety in the interim until new overpack standards are developed and are in production.

Based on the FAA testing, RSPA believes that any increase in risk posed by the presence of a compressed oxygen cylinder in a cargo compartment can be significantly reduced, or even eliminated, if the oxygen cylinder is placed in an outer packaging or overpack that provides more thermal protection and flame resistence than the ATA 300 overpacks currently in use. To this end, RSPA is developing proposed enhanced standards for outer packagings or overpacks to further protect cylinders from heat and fire. RSPA anticipates publishing an NPRM later this year to invite comments on enhanced standards for these outer packagings or overpacks, including a proposed date for their implementation. At present, RSPA is considering a requirement that an oxygen cylinder may be carried in an inaccessible cargo compartment on an aircraft only when the cylinder is placed in an outer packaging or overpack meeting certain flame penetration resistance, thermal protection, and integrity standards. The flame penetration standards would likely be similar to those specified for Class C cargo compartment liners in 14 CFR part 25, appendix F, part III.

If RSPA adopts enhanced standards for outer packagings or overpacks, we would require use of an enhanced outer packaging or overpack as soon as practicable. On the other hand, if RSPA ultimately concludes that enhanced standards will not provide significantly more thermal protection and heat penetration resistence than the ATA 300 overpacks currently in use, RSPA may prohibit the carriage of oxygen cylinders in inaccessible cargo compartments that do not have appropriate fire or smoke detection systems and fire suppression systems.

RSPA is also adopting stowage requirements and numerical limitations with regard to oxygen cylinders in aircraft cargo compartments—rather than completely prohibiting the transportation of oxygen cylinders in cargo compartments of passenger aircraft and in inaccessible cargo compartments on all-cargo aircraft. The temperatures of a fire in a cargo compartment are, for the most part, much higher at the top of the compartment than at the bottom. RSPA believes that stowing the cylinders horizontally on the floor of the compartment may decrease the likelihood that a cylinder exposed to a cargo compartment fire will vent. Therefore, RSPA is requiring that cylinders of compressed oxygen be placed horizontally on or as close as practicable to the floor of the cargo compartment or unit load device. RSPA also believes that only a limited number of cylinders should be transported in Class B and D cargo compartments in order to decrease the aggregate risk to the aircraft. Therefore, RSPA is limiting to six the number of cylinders that can be stowed in an aircraft in Class B compartments (accessible, no fire suppression systems) and Class D compartments (no fire or smoke detection or fire suppression systems). RSPA believes that the concerns expressed by foreign aircraft operators and aircraft operators in remote locations (e.g., Alaska) are addressed by continuing to allow oxygen cylinders to be transported aboard passenger-carrying aircraft.

As proposed in the SNPRM, this final rule will allow for the carriage of a limited number of oxygen cylinders, as cargo, in the passenger cabin of an aircraft, under certain conditions. This authorization is limited to no more than six airline-owned cylinders and one additional cylinder containing medical-use oxygen per passenger needing the oxygen at destination. However, consistent with the exemption on which the proposal was based (see SNPRM; 62 FR 44377), RSPA is limiting this allowance to small ''medical-use'' oxygen cylinders with capacities no greater than 850 liters (30 cubic feet). Consistent with the outer packaging requirements for other cargo compartments, RSPA is requiring that these cylinders be placed in an overpack or outer packaging that meets the requirements of ATA 300. This exception is provided to ensure that cylinders of medical oxygen owned by an airline or a passenger—requiring oxygen at destination—can continue to be transported aboard passenger-carrying aircraft.

The exception does not eliminate or waive any of the current packaging, maintenance, or use requirements of the HMR related to cylinders of compressed oxygen, or any of the FAA or airline security requirements. If an airline elects to accept for transportation passenger-owned oxygen cylinders in accordance with 175.10(b), the passenger will have to offer the cylinder to the airline in accordance with the

established procedures of the airline. These procedures may require passengers to tender their cylinders at airline cargo facilities or at passenger check-in counters. In addition, the passengers will not have access to their cylinders until they are returned to them by the airlines. Again, these procedures will be established by the airlines. RSPA notes that none of DOT's requirements require airlines to accept passengers' cylinders of compressed oxygen, nor do they require or preclude airlines from charging fees for this service. In addition, RSPA also notes that nothing in this rulemaking mandates that an airline supply the ATA 300 overpack. If an airline elects not to supply the ATA 300 overpack or outer packaging, its passengers will be responsible for obtaining the overpack or outer packaging.

New paragraph § 175.10(b) allows six oxygen cylinders owned or leased by the aircraft operator or a passenger to be transported as cargo in the cabin of the aircraft. These oxygen cylinders are hazardous materials, subject to all applicable HMR requirements. See the RSPA's ''Advisory Notice: Transportation of Air Carrier Company Materials (COMAT) by Aircraft,'' 61 FR 65479 (December 13, 1996). Air carriers who do not elect to accept or transport hazardous materials (and have not developed the manuals and trained their employees as required by 14 CFR) must offer their company-owned oxygen cylinders to a carrier of another mode (e.g., highway) or to another air carrier that has an established program for transportation of hazardous materials.

C. Spent Chemical Oxygen Generators

In the SNPRM, RSPA proposed to prohibit the transportation of spent chemical oxygen generators (i.e., generators in which the means of initiation and the chemical core have been expended) and to regulate them as Class 9 materials when transported by other means of transportation. All commenters supported this proposal. The NTSB stated that ''it is difficult to determine whether all of the oxidizing material in a spent generator has been depleted, since a generator is a closed container, and both the oxidizer within the generator before the reaction and the materials remaining in the generator after the reaction are solids with similar weights.''

RSPA believes that lessening the possibility that this type of human error may occur outweighs any interest in, or need for, transporting spent chemical oxygen generators by aircraft. Accordingly, RSPA is prohibiting the transportation by aircraft of spent chemical oxygen generators and to regulate them as Class 9 materials when transported by other than aircraft.

Based on the foregoing, RSPA is adding to the Hazardous Materials Table (HMT) the new shipping description, ''Oxygen generator, chemical, spent, 9, NA3356, III.'' The entry is preceded by a plus sign (''+'') in Column 1 to fix the proper shipping name, hazard class and packing group for the entry without regard to whether the material meets the definition of a Class 9 hazardous material. Special provision 61 is added in Column 7 to specify the conditions under which an oxygen generator is considered ''spent.'' In addition, ''None'' is added to Column 8A of the HMT because RSPA believes that spent oxygen generators should not be eligible for limited quantity exceptions or to be reclassified as a consumer commodity. RSPA is also amending §§ 171.11, 171.12 and 171.12a, consistent with the proposals, to indicate that there are no exceptions from HMR requirements for classification, description, and packaging of spent chemical oxygen generators when shipping to, from or within the U.S. under the provisions of international or Canadian regulations.

D. Personal Oxygen Generators

RSPA proposed to eliminate the exception in 49 CFR 175.10(a)(24) that allows the transportation of small personal oxygen generators in checked baggage. There was no opposition and a number of commenters, including the NTSB, expressed support for this proposal. The NTSB stated that this exception currently permits the placement of oxidizers in cargo compartments that do not have fire or smoke detection systems and that are designed to suppress a fire by limiting the oxygen available to support combustion and, therefore, it supports the proposal.

As proposed in the December 30, 1996 NPRM, RSPA is removing the exception provided in § 175.10(a)(24) for small personal chemical oxygen generators in checked baggage.

E. Other Materials

The NPRM and the SNPRM proposed to prohibit the transportation of packages required to be labeled OXIDIZER or OXYGEN on passenger aircraft and in inaccessible cargo compartments aboard cargo aircraft. Therefore, the proposed prohibition did not apply to an oxidizer classed as a consumer commodity, ORM–D, under the provisions of 49 CFR 173.152. The ICAO Technical Instructions do not allow Division 5.1 materials (oxidizers) to be reclassified as a consumer commodity. RSPA specifically requested comments regarding whether it would be appropriate to extend the prohibition to consumer commodities that are oxidizers or whether quantity limits should be imposed on these materials in 49 CFR 175.75.

In its comments, NTSB stated that it was concerned that the proposals did not include a prohibition on those oxidizers that are shipped as consumer commodities. It also stated that the exception in 49 CFR 173.152 allows the placement of oxidizers in cargo compartments that do not have fire or smoke detection/suppression systems and, therefore, urged that the consumer commodity exception for oxidizers be eliminated. NTSB also requested that RSPA include organic peroxides in its study of the effects of hazardous materials in cargo compartments fires and to ban them from transportation by air if they cannot be transported safely.

Other commenters stated that they opposed extending the prohibition to consumer commodity oxidizers. These commenters stated that these materials are adequately regulated under ICAO and 49 CFR 173.152. HMAC stated that penalizing those who comply with the regulations does not address the issues of untrained and undertrained personnel and undeclared and misdeclared hazardous materials nor does it improve safety for the general public. HMAC urged RSPA to focus on aggressively enforcing current regulations, educating the regulated community, and taking appropriate penalty actions against those that do not comply.

RSPA believes that those oxidizers authorized to be reclassed as ORM–D (i.e., consumer commodities) are of a form and quantity that would not pose an unacceptable risk to the safety of an aircraft, even in cargo compartments that lack a fire and smoke detection system. Therefore, RSPA is not prohibiting oxidizers that have been reclassed as an ORM–D from being transported in Class D cargo compartments. RSPA also believes that NTSB's request to include organic peroxides in the prohibition is outside the scope of this rulemaking and, therefore, has not been adopted. However, as noted in the December 30, 1996 NPRM, RSPA has initiated a study to assess the risks associated with the transportation of hazardous materials in aircraft cargo compartments that may result in RSPA publishing another rulemaking to ban additional hazardous materials. As part of that study, RSPA is reviewing the hazards posed by materials similar to oxidizers, such as organic peroxides.

IV. Regulatory Analyses and Notices

Executive Order 12866 and DOT Regulatory Policies and Procedures

This final rule is considered a significant regulatory action under section 3(f) of Executive Order 12866 and was reviewed by the Office of Management and Budget. The rule is considered significant under the regulatory policies and procedures of the Department of Transportation (44 FR 11034). A regulatory evaluation is available for review in the public docket.

Executive Order 12612

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 (''Federalism''). The Federal hazardous materials transportation law (49 U.S.C. 5101–5127) contains an express preemption provision that preempts State, local, and Indian tribe requirements on certain covered subjects. Covered subjects are:

(A) The designation, description, and classification of hazardous material;

(B) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(C) The preparation, execution, and use of shipping documents pertaining to hazardous material and requirements respecting the number, content, and placement of such documents;

(D) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(E) The design, manufacturing, fabrication, marking, maintenance, reconditioning, repairing, or testing of a package or container which is represented, marked, certified, or sold as qualified for use in the transportation of hazardous material.

Because RSPA lacks discretion in this area, preparation of a federalism assessment is not warranted.

Title 49 U.S.C. 5125(b)(2) provides that DOT must determine and publish in the **Federal Register** the effective date of Federal preemption. That effective date may not be earlier than the 90th day following the date of issuance of the final rule and not later than two years after the date of issuance. This rule requires oxidizers to be transported in certain types of cargo compartments aboard aircraft and specifies overpacking requirements for cylinder of compressed oxygen. RSPA determined that the effective date of Federal preemption for the requirements in this rule concerning covered subjects is March 1, 2000.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (the Act) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statues, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation.'' To achieve that principle, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rational for their actions. The Act covers a wide-range of small entities, including small businesses, not-for-profit organizations and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the determination is that it will, the agency must prepare a regulatory flexibility analysis (RFA) as described in the Act.

However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the Act provides that the head of the agency may so certify and an RFA is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This rule will prohibit the carriage of oxidizers onboard aircraft in inaccessible cargo compartments that do not have a fire or smoke detection system and a fire suppression system. This rule will affect persons who ship oxidizers by air and the airline operators that transport oxidizers as cargo. However, it is assumed that shippers will not have to pay more to ship oxidizers by alternative means: on all-cargo aircraft that have accessible cargo compartments or cargo compartments with a fire or smoke detection system and a fire suppression system, on passenger-carrying aircraft that have cargo compartments with a fire or smoke detection system and a fire suppression system, or by other modes of transportation. It is also assumed that there will be no loss of revenue for all-cargo operators because they can transport oxidizers in class E cargo compartments or (if the aircraft is so equipped) in class C cargo compartments.

Accordingly, this rule will only reduce the freight revenues of an operator of passenger-carrying aircraft that also carry oxidizers as cargo in compartments that do not have a fire or smoke detection system and a fire suppression system. The effect of this rule on an operator certificated under 14 CFR part 121 will only last until March 19, 2001, because the class D compartments on their aircraft (i.e., those compartments without a fire or smoke detection system and a fire suppression system) must meet the standards for a class C or class E compartment by that date.

In the SNPRM, RSPA evaluated the effect of its proposed rule on part 121 operators under FAA Order 2100.A and stated that it lacked sufficient data to determine the proposed rule's economic impact on entities other than those operating under 14 CFR part 121 (e.g., part 135 operators). Although RSPA requested comments ''on the economic impact, if any, of this proposed rule on other entities,'' no comments were submitted that would assist RSPA's evaluation of the impact of this rule on small entities.

Because the FAA no longer uses the criteria in its Order 2100.A to determine who are small entities, RSPA considers that an airline operator with fewer than 1,500 employees is a small entity, under the Small Business Administration's criteria in 13 CFR part 121. RSPA reviewed air carrier traffic and revenue statistics complied by DOT's Office of Airline Information and information provided by FAA as to the air carriers approved to transport hazardous materials. These sources indicate that there is only one part 121 air carrier with fewer than 1,500 employees that carries passengers and accepts oxidizers for transportation as cargo.

There are many air carriers certificated under 14 CFR part 135 that are approved by FAA to carry hazardous materials. Many of these carriers transport only cargo. In general, they provide on-demand, rather than schedule service, and the inaccessible cargo compartment on these aircraft are small. (Most of the cargo is carried in the main compartment when there are no passengers.) RSPA does not have information on which part 135 carriers carry passengers or, more importantly, whether any of them carry passengers and hazardous materials on the same flight. Because of their limited cargo capacity and lack of schedule service, however, RSPA assumes that the passenger-carrying aircraft operated by part 135 carriers are not utilized for the transportation of oxidizers.

Accordingly, RSPA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 13084

RSPA believes that this final rule will have no significant or unique effect on the communities of Indian tribal governments when analyzed under the principles and criteria contained in Executive Order 13084 (''Consultation and Coordination with Indian Tribal Governments''). Therefore, the funding and consultation requirements of this Executive Order do not apply.

Unfunded Mandates Reform Act of 1995

This final rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It will not result in costs of $100 million or more, in the aggregate, to any of the following: State, local, or Native American tribal governments, or the private sector. This final rule is the least burdensome alternative that achieves the objective of the rule.

Impact on Business Processes and Computer Systems (Year 2000)

Many computers that use two digits to keep track of dates may, on January 1, 2000, recognize ''double zero'' not as 2000 but as 1900. This Year 2000 problem could cause computers to stop running or to start generating erroneous data. The Year 2000 problem poses a threat to the global economy in which Americans live and work. With the help of the President's Council on Year 2000 Conversion, Federal agencies are reaching out to increase awareness of the problem and to offer support. We do not want to impose new requirements that would mandate business process changes when the resources necessary to implement those requirements would otherwise be applied to the Year 2000 problem.

This final rule does not impose business process changes or require modification to computer systems. Because the final rule does not affect organizations' ability to respond to the Year 2000 problem, we do not intend to delay the effectiveness of the requirements in the final rule.

Paperwork Reduction Act

This final rule does not impose any new information collection requirements.

Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

49 CFR Part 172

Education, Hazardous materials transportation, Hazardous waste, Labeling, Marking, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 175

Air carriers, Hazardous materials transportation, Radioactive materials, Reporting and recordkeeping requirements.

In consideration of the foregoing, 49 CFR Parts 171, 172, and 175 are amended as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

1. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

2. In 171.7, in the Table of material incorporated by reference in paragraph (a)(3), a new entry is added in appropriate alphabetical order to read as follows:

§ 171.7 Reference material.

(a) * * *

(3) * * *

Source and name of material	49 CFR reference
Air Transport Association of America, 1301 Pennsylvania Avenue, N.W., Washington, DC 20004–1707	.....
ATA Specification No. 300 Packaging of Airline Supplies, Revision 19, July 31, 1996	172.102
* * * * *	

* * * * *

3. In § 171.11, paragraph (d)(15) is revised and paragraph (d)(16) is added to read as follows:

§ 171.11 Use of ICAO Technical Instructions.

* * * * *

(d) * * *

(15) A chemical oxygen generator is forbidden for transportation aboard a passenger-carrying aircraft and must be approved, classed, described and packaged in accordance with the requirements of this subchapter for transportation on cargo-only aircraft. A chemical oxygen generator (spent) is forbidden for transportation on aircraft.

(16) A cylinder containing Oxygen, compressed, may not be transported on a passenger-carrying aircraft or in an inaccessible cargo location aboard a cargo-only aircraft unless it is packaged as required by Part 173 and Part 178 of this subchapter and is placed in an overpack or outer packaging that satisfies the requirements of Special Provision A52 in § 172.102.

4. In § 171.12, paragraph (b)(18) is revised to read as follows:

§ 171.12 Import and export shipments.

* * * * *

(b) * * *

(18) A chemical oxygen generator must be approved in accordance with the requirements of this subchapter. A chemical oxygen generator and a chemical oxygen generator (spent) must be classed, described and packaged in accordance with the requirements of this subchapter.

* * * * *

5. In § 171.12a, paragraph (b)(17) is revised to read as follows:

§ 171.12a Canadian shipments and packagings.

* * * * *

(b) * * *

(17) A chemical oxygen generator must be approved in accordance with the requirements of this subchapter. A chemical oxygen generator and a chemical oxygen generator (spent) must be classed, described and packaged in accordance with the requirements of this subchapter.

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, AND TRAINING REQUIREMENTS

6. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

7. In the § 172.101 Hazardous Materials Table, one entry is added in appropriate alphabetical order and one entry is revised to read as follows:

§ 172.101 Purpose and use of hazardous materials table.

* * * * *

§ 172.101.—HAZARDOUS MATERIALS TABLE

Symbols	Hazardous materials descriptions and proper shipping names	Hazard class or division	Identification numbers	PG	Label codes	Special provisions	(8) Packaging authorizations (§ 173.***)			(9) Quantity limitations		(10) Vessel stowage requirements	
							Exceptions	Non-bulk	Bulk	Passenger aircraft/rail	Cargo aircraft only	Location	Other
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
	[Revised]												
	*	*		*		*		*		*		*	
	Oxygen, compressed.	2.2	UN1072		2.2, 5.1 ..	A52	306 ...	302	314, 315.	75 kg	150 kg	A	
	*	*		*		*		*		*		*	
	[Added]												
	*	*		*		*		*		*		*	
+	Oxygen generator, chemical, spent.	9	NA3356	III	9	61	None	213	None	Forbidden	Forbidden	A	
	*	*		*		*		*		*		*	

8. In § 172.102, special provision ''61'' is added in appropriate numerical sequence to paragraph (c)(1) and special provision ''A52'' is added in alphanumeric sequence to paragraph (c)(2), to read as follows:

§ 172.102 Special provisions.

* * * * *

(c) * * *

(1) * * *

Code/Special Provisions

* * * * *

61 A chemical oxygen generator is spent if its means of ignition and all or a part of its chemical contents have been expended.

* * * * *

(2) * * *

Code/Special Provisions

* * * * *

A52 A cylinder containing Oxygen, compressed, may not be loaded into a passenger-carrying aircraft or in an inaccessible cargo location on a cargo-only aircraft unless it is placed in an overpack or outer packaging that conforms to the performance criteria of Air Transport Association (ATA) Specification 300 for Type I shipping containers.

* * * * *

PART 175—CARRIAGE BY AIRCRAFT

9. The authority citation for part 175 continues to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

10. In § 175.10, paragraph (b) is added to read as follows:

§ 175.10 Exceptions.

* * * * *

(b) A cylinder containing medical-use compressed oxygen, owned or leased by an aircraft operator or offered for transportation by a passenger needing it for personal medical use at destination, may be carried in the cabin of a passenger-carrying aircraft in accordance with the following provisions:

(1) No more than six cylinders belonging to the aircraft operator and, in addition, no more than one cylinder per passenger needing the oxygen at destination, may be transported in the cabin of the aircraft under the provisions of this paragraph (b);

(2) The rated capacity of each cylinder may not exceed 850 liters (30 cubic feet);

(3) Each cylinder and its overpack or outer packaging (see Special Provision A52 in § 172.102 of this subchapter) must conform to the provisions of this subchapter;

(4) The aircraft operator shall securely stow the cylinder in its overpack or outer packaging in the cabin of the aircraft and shall notify the pilot-in-command as specified in § 175.33 of this part; and

(5) Shipments under this paragraph (b) are not subject to—

(i) Subpart C and, for passengers only, subpart H of part 172 of this subchapter;

(ii) Section 173.25(a)(4) of this subchapter.

(iii) Section 175.85(i).

§ 175.10 [Amended]

11. In addition, in § 175.10 paragraph (a)(24) is removed and reserved.

12. In § 175.85, paragraphs (h) and (i) are added to read as follows:

§ 175.85 Cargo location.

* * * * *

(h) Compressed oxygen, when properly labeled Oxidizer or Oxygen, may be loaded and transported as provided in paragraph (i) of this section. No person may load or transport any other package containing a hazardous material for which an OXIDIZER label is required under this subchapter in an inaccessible cargo compartment that does not have a fire or smoke detection system and a fire suppression system.

(i) In addition to the quantity limitations prescribed in § 175.75, cylinders of compressed oxygen must be stowed in accordance with the following:

(1) No more than a combined total of six cylinders of compressed oxygen may be stowed on an aircraft in the inaccessible aircraft cargo compartment(s) that do not have fire or smoke detection systems and fire suppression systems.

(2) When loaded into a passenger-carrying aircraft or in an inaccessible cargo location on a cargo-only aircraft, cylinders of compressed oxygen must be stowed horizontally on the floor or as close as practicable to the floor of the cargo compartment or unit load device. This provision does not apply to cylinders stowed in the cabin of the aircraft in accordance with § 175.10(b).

(3) When transported in a Class B aircraft cargo compartment (see 14 CFR 25.857(b)) or its equivalent (i.e., an accessible cargo compartment equipped with a fire or smoke detection system but not a fire suppression system), cylinders of compressed oxygen must be loaded in a manner that a crew member can see, handle and, when size and weight permit, separate the cylinders from other cargo during flight. No more than six cylinders of compressed oxygen

and, in addition, one cylinder of medical-use compressed oxygen per passenger needing oxygen at destination—with a rated capacity of 850 liters (30 cubic feet) or less of oxygen—may be carried in a Class B aircraft cargo compartment or its equivalent.

Issued in Washington, DC on August 11, 1999 under the authority delegated in 49 CFR part 1.

Kelley S. Coyner,

Administrator.

[FR Doc. 99–21187 Filed 8–18–99; 8:45 am]

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Thursday
August 19, 1999

Part VI

Department of the Interior

Fish and Wildlife Service

50 CFR Part 20

Migratory Bird Hunting; Final Approval of Tungsten-Iron and Tungsten-Polymer Shots and Temporary Approval of Tungsten-Matrix and Tin Shots as Nontoxic for Hunting Waterfowl and Coots; Final Rule

DEPARTMENT OF INTERIOR

Fish and Wildlife Service

50 CFR Part 20

RIN 1018–AF65

Migratory Bird Hunting; Final Approval of Tungsten-Iron and Tungsten-Polymer Shots and Temporary Approval of Tungsten-Matrix and Tin Shots as Nontoxic for Hunting Waterfowl and Coots

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service or we) amends Section 20.21(j) to grant final approval of tungsten-iron and tungsten-polymer shots as nontoxic for hunting waterfowl and coots. We also grant temporary approval of tungsten-matrix and tin shots as nontoxic for hunting waterfowl and coots during the 1999–2000 hunting season only. Acute toxicity studies reveal no adverse effects over a 30-day period on mallards (*Anas platyrhynchos*) dosed with either tungsten-iron, tungsten-polymer, tungsten-matrix, or tin shot. Reproductive/chronic toxicity testing over a 150-day period indicated that tungsten-iron and tungsten-polymer administered to adult mallards did not adversely affect them or the offspring they produced. We will not consider final approval of tungsten-matrix and tin shots until all required reproductive/chronic toxicity tests are successfully completed and the results are received and approved by the Director. Tungsten-iron and tungsten-polymer shots are produced by Federal Cartridge Company (Federal) of Anoka, Minnesota. Tungsten-matrix shot is produced by Kent Cartridge Company (Kent) of Kearneysville, West Virginia. Tin shot is produced by the International Tin Research Institute (ITRI) of Uxbridge, Middlesex, Great Britain.

DATES: This rule takes effect immediately upon publication on August 19, 1999.

ADDRESSES: Copies of the Environmental Assessments are available by writing to the Chief, Office of Migratory Bird Management (MBMO), U.S. Fish and Wildlife Service, 4401 N. Fairfax Dr., Suite 634, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Jon Andrew, Chief, Office of Migratory Bird Management, (703) 358–1714.

SUPPLEMENTARY INFORMATION: Since the mid-1970s, we have sought to identify shot that does not pose a significant toxic hazard to migratory birds or other wildlife. Currently, only steel and bismuth-tin shot are approved as nontoxic. We previously granted temporary approval for tungsten-iron shot during the 1997–98 (August 13, 1997; 62 FR 43444) and 1998–99 (October 7, 1998; 63 FR 54016) migratory bird hunting seasons. We also granted temporary approval for tungsten-polymer (October 7, 1998; 63 FR 54022) and tungsten-matrix (December 8, 1998; 63 FR 67619) shots during the 1998–99 migratory bird hunting season. Compliance with the use of nontoxic shot has increased over the last few years. We believe that compliance will continue to increase with the approval and availability of other nontoxic shot types.

Federal Cartridge Company's (Federal) tungsten-iron shot is an alloy of approximately 40 percent tungsten and 60 percent iron, by weight, and has a density of approximately 10.3 g/cm^3. Tungsten-polymer shot is a matrix of Nylon 6 or 11 polymer surrounding particles of elemental tungsten. Shot made from this material has a density of approximately 11.2 g/cm^3 or approximately the density of lead. The shot will contain approximately 95.5 percent tungsten and 4.5 percent Nylon 6 or 11 by weight).

Kent's original candidate shot was fabricated from what is described in their application as a mixture of powdered metals in a plastic matrix whose density is comparable to that of lead. All component metals are present as elements, not compounds. The tungsten-matrix material from which pellets are formulated has a specific gravity of 9.8 g/cm^3 and is composed of 88 percent tungsten, 4 percent nickel, 2 percent iron, 1 percent copper, and 5 percent polymers by mass. After consultation with us, Kent has subsequently changed the composition of their shot and removed nickel and copper. The new shot material being considered has a density of 10.7 g/cm^3 and is composed of approximately 95.9 percent tungsten and 4.1 percent polymers.

ITRI's candidate shot is made from commercially pure tin; no alloying or other alterations are intentionally made to the chemical composition of the shot. This shot material has a density of approximately 7.29 g/cm^3, and is 99.9 percent tin, with a low level of iron pickup due to the steel production equipment.

Each of Federal's applications for tungsten-iron and tungsten-polymer include a description of the shot, a toxicological report (Barr 1996), results of a 30-day dosing study of the toxicity of the shot in game-farm mallards (Bursian et al. 1996a, Bursian et al. 1996b), and results of a 150-day reproductive/chronic toxicity study (Bursian et al. 1999). Kent's application for tungsten-matrix includes a description of the shot, a toxicological report (Thomas 1997a), and results of a 30-day toxicity study (Wildlife International, Ltd. 1998a). The tin shot application from ITRI contains a description of the shot, a toxicological report (Thomas 1997b), and results of a 30-day toxicity study (Wildlife International, Ltd. 1998b). Toxicological reports for each shot type incorporates toxicity information (a synopsis of acute and chronic toxicity data for mammals and birds, potential for environmental concern, and toxicity to aquatic and terrestrial invertebrates, amphibians and reptiles) and information on environmental fate and transport (shot alteration, environmental half-life, and environmental concentration).

Toxicity Information

There is considerable difference in the toxicity of soluble and insoluble compounds of tungsten and iron. Elemental tungsten and iron are virtually insoluble and are therefore expected to be relatively nontoxic. Even though most toxicity tests reviewed were based on soluble tungsten compounds rather than elemental tungsten, there appears to be no basis for concern of toxicity to wildlife for either candidate shot via ingestion by fish or mammals (Bursian et al. 1996b, Gigiena 1983, Karantassis 1924, Patty 1982, Industrial Medicine 1946). Detailed reviews of the toxicological impacts of different tin compounds have been conducted by Eisler (1989) and Cooney (1988). Both reviews indicate that elemental tin is non-toxic to animals. Tin shot designed for waterfowl hunting is utilized in several European countries and no reports exist that suggest that tin shot is causing toxicity problems for wildlife in those countries.

The potential toxicity of nylon compounds due to degradation is primarily associated with the stabilizers, antioxidants, plasticizers, and unreacted prepolymers. Residual caprolactum has been found in some commercial Nylon 6 products, but little concern regarding this compound has been developed (Patty, 1982). The toxicity of Nylon 6 and 11 are negligible due to their insolubilities.

Environmental Fate and Transport

Tungsten is insoluble in water and therefore not mobile in hypergenic

environments. Tungsten is very stable with acids and does not easily complex. Preferential uptake by plants in acid soil suggests uptake of tungsten in the anionic form associated with tungsten minerals rather than elemental tungsten (Kabata and Pendias 1984). Tin pellets will undergo slow surface oxidation to form hydrated tin oxide, which is extremely insoluble in water (Lide 1990). Therefore dissolution will be slow, and highly localized aqueous concentrations will not arise. This means that elemental tin will over time remain largely in the same inorganic form as when it is discharged. Tin pellets discharged into wetlands where sulphur ions are released during organic decomposition would become coated with tin sulphide, which is highly insoluble in water and resistant to aquatic hydrolysis (Hoiland 1995).

Environmental Concentration

The effective environmental concentration (EEC) for a terrestrial ecosystem was calculated based on 69,000 shot per hectare (Pain 1990), assuming complete erosion of material in 5 cm of soil. For tungsten-iron shot, the EEC for tungsten in soil was calculated at 32.9 mg/kg. For tungsten-polymer shot, the EECs for tungsten and Nylon (6 and 11) in soil are 58.3 mg/kg and 2.7 mg/kg, respectively. The EECs for tungsten and the 2 polymers found in tungsten-matrix are 25.7 mg/kg, 4.2 mg/kg, and 0.14 mg/kg, respectively. The EEC for tin in soil is 19.3 g/m^3.

The environmental concentration (EEC) for an aquatic ecosystem was calculated assuming complete erosion of the shot in one cubic foot of water. For tungsten-iron shot, the EEC in water for tungsten was 10.5 mg/L. For tungsten-polymer shot, the EECs in water for tungsten and Nylon (6 and 11) are 18.7 mg/L and 0.9 mg/L, respectively. The EECs in water for tungsten and the 2 polymers found in tungsten-matrix are 4.2 mg/L, 0.2 mg/L, and 0.02 mg/L, respectively. The EEC in water for tin is 19.3 mg/L.

Effects on Birds

An extensive literature review in each application provided information on the toxicity of elemental tungsten and tin to waterfowl and other birds. Ringelman et al. (1993) orally dosed 20 8-week-old game-farm mallards with 12–17 (1.03 g average weight) tungsten-bismuth-tin (TBT) pellets and monitored them for 32 days for evidence of intoxication. No birds died during the trial, gross lesions were not observed during the postmortem examinations, histopathological examinations did not reveal any evidence of toxicity or tissue damage, and tungsten was not detectable in kidney or liver samples. The authors concluded that TBT shot presented virtually no potential for acute intoxication in mallards.

Kraabel et al. (1996) assessed the effects of embedded TBT shot on mallards and concluded that TBT was not acutely toxic when implanted in muscle tissue. Inflammatory reactions to TBT shot were localized and had no detectable systemic effects on mallard health.

Nell (1981) fed laying hens (*Gallus domesticus*) 0.4 or 1.0 g/kg tungsten in a commercial mash for five months to assess reproductive performance. Weekly egg production was normal and hatchability of fertile eggs was not affected. Exposure of chickens to large doses of tungsten either through injection or by feeding resulted in an increased tissue concentration of tungsten and a decreased concentration of molybdenum (Nell 1981). The loss of tungsten from the liver occurred in an exponential manner with a half-life of 27 hours. The alterations in molybdenum metabolism seemed to be associated with tungsten intake rather than molybdenum deficiency. Death due to tungsten occurred when tissue concentrations increased to 25 mg/g liver. At that concentration, xanthine dehydrogenase activity was zero.

Ringelman et al. (1992) conducted a 32-day acute toxicity study which involved dosing game-farm mallards with a shot alloy of tungsten-bismuth-tin (TBT), which was 39, 44.5 and 16.5 percent by weight, respectively. No dosed birds died during the trial, and behavior was normal. Examination of tissues post-euthanization revealed no toxicity or damage related to shot exposure. This study concluded that ''. . . TBT shot presents virtually no potential for acute intoxication in mallards under the conditions of this study.''

Several studies have been conducted in which pellets made of tin or tin alloys have been placed inside the digestive tract or tissues of ducks to determine if toxic effects occur. Grandy et al. (1968) and the Huntingdon Research Centre (1987) conducted 30- and 28-day, respectively, acute toxicity tests on mallard ducks and reported that all treatment ducks survived with insignificant weight loss or development of pathological lesions. The potential for bismuth-tin (BT) shot to produce toxicological effects in ducks during reproduction has been investigated under both acute and chronic testing conditions. Tin as a 2% component of the tested shot, did not pose a toxic risk to ducks when fed a nutritionally-imbalanced, corn-based diet. Neither has BT shot been shown to pose an adverse risk to the health of ducks, the reproduction by male and female birds, nor the survival of ducklings over the long term (Sanderson et al. 1997a,b).

Nylon 6 is the commercially important homopolymer of caprolactum. Most completely polymerized nylon materials are physiologically inert, regardless of the toxicity of the monomer from which they are made (Peterson 1977). Few data exist on the toxicity of Nylon 6 in animals. Most toxicity studies are related to thermal degradation products and so are not relevant to the exposure of wildlife to shot containing nylon. Montgomery (1982) reported that feeding Nylon 6 to rats at a level of 25 percent of the diet for 2 weeks caused a slower rate of weight gain, presumably due to a decrease in food consumption and feed efficiency. However, the rats suffered no anatomic injuries due to the consumption of nylon.

The two plastic polymers used in tungsten-matrix shot act as a physical matrix in which the tungsten is distributed as ionically-bound fine particles. Most completely polymerized nylon materials are physiologically inert, regardless of the toxicity of the monomer from which they are made (Peterson 1977). A literature review did not reveal studies in which either of the two polymers were evaluated for toxicity in birds.

Acute Toxicity Studies

Federal contracted with Michigan State University—Department of Animal Science, to conduct an acute toxicity study of tungsten-iron and tungsten-polymer. Both Kent and ITRI contracted with Wildlife International Ltd. to conduct an acute toxicity study of tungsten-matrix and tin shots, respectively. The acute toxicity test is a short-term (30-day) study where ducks are dosed with shot and fed commercially available duck food. Survival, body weight, blood hematocrit, and organ analysis are recorded.

Tungsten-iron and tungsten-polymer

The 30-day dosing study revealed no adverse effects when mallards were dosed with either 8 BB size tungsten-iron shot or 8 BB size tungsten-polymer shot and monitored over a 30-day period (Bursian et al. 1996a, Bursian et al. 1996b). Eight male and 8 female adult mallards were dosed with either 8 No.4 steel shot, 8 No.4 lead shot, 8 BB size tungsten-iron shot, or 8 BB size tungsten-polyer shot and observed over

a 30-day period. An additional 8 males and 8 females received no shot. Fifty percent of the lead-dosed birds (5 males and 3 females) died during the 30-day test while there were no mortalities in the other groups. Lead-dosed birds were the only ones to display green excreta, lethargy, and ataxia. Body weights were not significantly altered by any of the treatments, although lead-dosed birds which died during the trial lost an average of 30 percent of their body weight. Hematocrit, hemoglobin concentrations, and ALAD activity were significantly depressed at day 15 in the lead-dosed females, while lead-dosed males had significantly depressed hematocrit and hemoglobin concentration compared with the other four groups. There were no significant differences in these whole-blood parameters at day 30. Three tungsten-polymer-dosed males developed mild biliary stasis. The authors attributed this to the intubating of mallards with 8 BBs of tungsen-polymer shot inducing a pathological condition—however slight—that was not found in the control birds. No other histopathological lesions were found. Tungsten was detected in the femur of two tungsten-polymer-dosed females and the kidneys of two tungsten-polymer-dosed birds; in both tissues, concentrations were only slightly above detection limits. In general, no adverse effects were seen in mallards given 8 BB-size tungsten-polymer shot and monitored over a 30-day period.

Tungsten-matrix

Kent's 30-day dosing study (Wildlife International Ltd. 1998a) included 4 treatment and 1 control group of game-farm mallards. Treatment groups were exposed to 1 of 3 different types of shot: 8 #4 steel, 8 #4 lead, or 8 #4 tungsten-matrix; whereas the control group received no shot. The 2 tungsten-matrix treatment groups (1 group deficient diet, 1 group balanced diet) each consisted of 16 birds (8 males and 8 females); whereas remaining treatment and control groups consisted of 6 birds each (3 males and 3 females). All tungsten-matrix-dosed birds survived the test and showed no overt signs of toxicity or treatment-related effects on body weight. There were no differences in hematocrit or hemoglobin concentration between the tungsten-matrix treatment group and either the steel shot or control groups. No histopathological lesions were found during gross necropsy. In general, no adverse effects were seen in mallards given 8 #4 size tungsten-matrix shot and monitored over a 30-day period. Tungsten was found to be below the limit of detection in all samples of femur, gonad, liver, and kidney from treatment groups.

Tin

ITRI's 30-day dosing study (Wildlife International Ltd. 1998b) included 4 treatment and 1 control group of game-farm mallards. Treatment groups were exposed to 1 of 3 different types of shot: 8 #4 steel, 8 #4 lead, or 8 #4 tin shot; whereas the control group received no shot. The 2 tin treatment groups (1 group deficient diet, 1 group balanced diet) each consisted of 16 birds (8 males and 8 females); whereas remaining treatment and control groups consisted of 6 birds each (3 males and 3 females). All tin-dosed birds survived the test and showed no overt signs of toxicity or treatment-related effects on body weight. There were no differences in hematocrit or hemoglobin concentration between the tin treatment group and either the steel shot or control groups. No histopathological lesions were found during gross necropsy. In general, no adverse effects were seen in mallards given 8 #4 size tin shot and monitored over a 30-day period. No levels of tin above the limit of detection were observed in any tissues collected from either tin treatment group.

Reproductive/Chronic Toxicity Study

Federal contracted with Michigan State University—Department of Animal Science, to conduct an a reproductive/chronic toxicity studies for both tungsten-iron and tungsten-polymer shot types. The reproductive/chronic toxicity study is a long-term (150-day) study where ducks are dosed with shot and fed commercially available duck food. Survival, body weight, blood hematocrit, organ analysis, and reproductive performance are recorded.

Tungsten-Iron and Tungsten-Polymer

The reproductive/chronic toxicity study revealed no adverse effects when mallards were dosed with either 8 No. 4 size tungsten-iron shot, or 8 No. 4 size tungsten-polymer shot, and monitored over a 150-day period (Bursian et al. 1999). Sixteen male and 16 female adult mallards were orally dosed with either 8 No.4 steel shot, 8 No.4 tungsten-iron shot, or 8 No. 4 tungsten-polymer shot. An additional 6 male and 6 female mallards were dosed with 8 No. 4 lead shot. All lead-dosed birds died by day 25 of the study, whereas no mortalities occurred in the other test groups. Lead-dosed birds had significantly decreased hematocrit, hemoglobin concentration and whole-blood delta aminolevulinic dehydratase activity on day 7 of the study. Mallards dosed with tungsten-iron or tungsten-polymer shot had occasional significant differences in hematocrit and plasma chemistry values when compared to steel-dosed mallards over the 150-day period, but these changes were within the normal range reported for mallards and were not considered to be deleterious. Relative kidney, heart, brain and gizzard weights of lead-dosed birds were significantly greater in comparison to relative weights of those organs in the other 3 treatment groups. Marked liver hemosiderosis was present in all steel and tungsten-dosed males, in 5 of 8 steel-and 3 of 8 tungsten-iron-dosed females, and in 1 tungsten-polymer-dosed male examined. Small amounts of tungsten were detected in gonad and kidney samples from males and females, in femur samples of males, and in liver samples from females dosed with tungsten-polymer shot. Higher concentrations of tungsten were detected in femur, gonad, kidney, and liver samples from tungsten-iron-dosed ducks. The rate of shot erosion was 99% for tungsten-polymer, 72% for tungsten-iron, 55% for steel, and 37% for lead. There were no significant differences in percent egg production, and percent fertility and hatchability of eggs from tungsten-iron- and tungsten-polymer-dosed ducks when compared to steel-dosed ducks. There were no biological differences in percent survivability and body weight of ducklings from tungsten-iron-or tungsten-polymer-dosed ducks when compared to ducklings from steel-dosed ducks. The hematocrit of ducklings from tungsten-iron-dosed ducks was slightly but significantly lower when compared to ducklings from steel-dosed ducks. Histological examination of duckling kidneys and liver indicated no abnormalities. Tungsten was detected in 25%, 9%, and 13% of the femur, kidneys, and liver samples, respectively, from ducklings of the tungsten-iron and tungsten-polymer groups. Overall, results of this study indicated that tungsten-iron and tungsten-polymer shot repeatedly administered to adult mallards did not adversely affect them or the offspring they produced during the 150-day trial.

Nontoxic Shot Approval

The first condition of nontoxic shot approval is toxicity testing. Based on the results of the toxicological report and the toxicity tests (Tiers 1, 2, and 3) discussed above, we conclude that tungsten-iron and tungsten-polymer shot does not pose a significant danger to migratory birds or other wildlife and their habitats. Based on the results of toxicological reports and acute toxicity tests (Tier 1 and 2), we conclude that tungsten-matrix and tin shots do not

appear to pose a significant danger to migratory birds or other wildlife and their habitats. However, final approval of either shot type will not be considered until all required reproductive/chronic toxicity tests have been successfully completed and our Director has reviewed and approved the results.

The second condition of approval is testing for residual lead levels. Any shot with lead levels equal to or exceeding 1 percent will be considered toxic and, therefore, illegal. We have determined that the maximum environmentally acceptable level of lead in any nontoxic shot is trace amounts of <1 percent, and incorporated this requirement in the nontoxic shot approval process that was published on December 1, 1997 (62 FR 63608). Federal has documented that tungsten-iron and tungsten-polymer shots meet this requirement. Kent and ITRI have documented that tungsten-matrix and tin shot, respectively, meet this requirement.

The third condition of approval involves enforcement. In the August 18, 1995, **Federal Register** (60 FR 43314), we indicated that approval of any nontoxic shot would be contingent upon the development and availability of a noninvasive field testing device. This requirement was incorporated in the nontoxic shot approval process that was published on December 1, 1997 (62 FR 63608). Tungsten-iron shotshells can be drawn to a magnet as a simple field detection method. Electronic field testing devices can distinguish shells containing tungsten-polymer and tungsten-matrix from shells containing lead. At the present time, we are not aware of any noninvasive field testing devices for distinguishing shells containing tin shot from those containing lead. We will not consider final approval of tin shot until such a device, or other noninvasive field testing method, has been developed for identifying tin shot.

In summary, this rule amends 50 CFR 20.21(j) by approving tungsten-iron and tungsten-polymer shots as nontoxic for migratory bird hunting. It is based on the toxicological reports, acute toxicity studies, and reproductive/chronic toxicity studies submitted by Federal. Results of these studies indicate the absence of any deleterious effects of tungsten-iron or tungsten-polymer shot when ingested by captive-reared mallards or to the ecosystem. This rule also grants temporary approval to tungsten-matrix and tin shots for the 1999–2000 hunting season only. Temporary approval is based on the toxicological reports and acute toxicity studies submitted by Kent and ITRI.

During the 1998–99 hunting season, we granted temporary approval of several shot types that contained tungsten (October 7, 1998, 63 FR 54016–54026; December 8, 1998, 63 FR 67619). We gave these approvals with the restriction that the shot types could not be used in the Yukon-Kuskokwim (Y–K) Delta, Alaska. This restriction was implemented out of concern for potential effects of tungsten on the spectacled eider (Somateria fischeri); a species subject to adverse weather, predation, and lead poisoning on the Y–K Delta. Based on the results of reproductive/chronic toxicity studies of tungsten-iron and tungsten-polymer, we see no need for the Y–K Delta restriction on any tungsten-based shot types.

Public Comments and Responses

We invited public comments from interested parties in the June 17, 1999, proposed rule published in the **Federal Register** (64 FR 32752). During the 30-day comment period, we received 4 comments.

The Wildlife Legislative Fund of America strongly supported the temporary approval of tungsten-matrix and tin shots for hunting migratory birds in order to provide additional nontoxic shot alternatives to hunters.

Senator John D. Rockefeller IV also supported the temporary approval of tungsten-matrix shot.

Kent acknowledged the conditions for nontoxic approval and indicated that chronic toxicity/reproductive test results for tungsten-matrix shot are proceeding satisfactorily.

ITRI indicated that chronic toxicity/reproductive tests are being completed for tin shot and a noninvasive field testing device will be available.

Service Response: We are encouraged that chronic toxicity/reproductive testing is being completed for tungsten-matrix and tin shots, and look forward to reviewing results of such tests when they become available. It is our hope that providing additional nontoxic shot alternatives will improve hunter compliance and reduce the amount of lead shot in the environment.

Effective Date

Under the APA (5 U.S.C. 553 (d)) we waive the 30-day period before this rule becomes effective and find that ''good cause'' exists, within the terms of 5 U.S.C. 553(d)(3) of the APA, and this rule will, therefore, take effect immediately upon publication. This rule relieves a restriction and, in addition, it is not in the public interest to delay the effective date of this rule. It is in the best interest of migratory birds and their habitats to grant approval to tungsten-iron and tungsten-polymer shot as nontoxic for hunting migratory birds, and to grant temporary approval to tungsten-matrix and tin shot for the 1998–99 migratory bird hunting season only. It is in the best interest of the hunting public to provide them an additional legal option for hunting waterfowl and coots for the 1999–2000 season, which begins on September 1, 1999. It is in the best interest of small retailers who have stocked the above shot types for the current season. We believe that availability of additional nontoxic shot options likely will improve hunter compliance, thereby reducing the amount of lead shot in the environment.

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NEPA Consideration

In compliance with the requirements of section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(C)), and the Council on Environmental Quality's regulation for implementing NEPA (40 CFR 1500–1508), we prepared Environmental Assessments (EA) in July, 1999. The EAs are available to the public at the location indicated under the **ADDRESSES** caption. Based on review and evaluation of the information in the EAs, we have determined that amending 50 CFR 20.21(j) to provide final approval of tungsten-iron and tungsten-polymer shots, and temporary approval of tungsten-matrix and tin shots for the 1999–2000 season, as nontoxic for migratory bird hunting would not be a major Federal action that would significantly affect the quality of the human environment.

Endangered Species Act Considerations

Section 7 of the Endangered Species Act (ESA) of 1972, as amended (16 U.S.C. 1531 *et seq.*), provides that Federal agencies shall ''insure that any action authorized, funded or carried out * * * is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of (critical) habitat * * *'' We have completed a Section 7 consultation under the ESA for this rule, which stated the use of tungsten-iron, tungsten-polymer, tungsten-matrix, and tin shots is not likely to adversely affect listed species. The result of our consultation under Section 7 of the ESA is available to the public at the location indicated under the **ADDRESSES** caption.

Regulatory Flexibility Act; Small Business Regulatory Enforcement and Fairness Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires the preparation of flexibility analyses for rules that will have a significant effect on a substantial number of small entities, which includes small businesses, organizations or governmental jurisdictions. This rule approves additional types of nontoxic shot that may be sold and used to hunt migratory birds; this rule provides 4 types of shot in addition to the existing 2 that are approved. We have determined, however, that this rule will have no effect on small entities since the approved shots merely will supplement nontoxic shot already in commerce and available throughout the retail and wholesale distribution systems. We anticipate no dislocation or other local effects, with regard to hunters and others. Similarly, this is not a major rule under 5 U.S.C. 804(2).

Executive Order 12866

This rule is not subject to Office of Management and Budget (OMB) review under Executive Order 12866. E.O. 12866 requires each agency to write regulations that are easy to understand. We invite comments on how to make this rule easier to understand, including answers to questions such as the following: (1) Are the requirements in the rule clearly stated? (2) Does the rule contain technical language or jargon that interferes with its clarity? (3) Does the format of the rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? (4) Would the rule be easier to understand if it were divided into more (but shorter) sections? (5) Is the description of the rule in the ''Supplementary Information'' section of the preamble helpful in understanding the rule? What else could we do to make the rule easier to understand?

Paperwork Reduction Act

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. We have examined this regulation under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501) and found it to contain no information collection requirements. However, we do have OMB approval (1018–0067; expires 06/30/2000) for information collection relating to what manufacturers of shot are required to provide to us for the nontoxic shot approval process. For further information see 50 CFR 20.134.

Unfunded Mandates Reform

We have determined and certify pursuant to the Unfunded Mandates Act, 2 U.S.C. 1502, *et seq.*, that this rulemaking will not impose a cost of $100 million or more in any given year on local or State government or private entities.

Civil Justice Reform—Executive Order 12988

We, in promulgating this rule, have determined that these regulations meet the applicable standards provided in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Takings Implication Assessment

In accordance with Executive Order 12630, these rules, authorized by the Migratory Bird Treaty Act, do not have significant takings implications and do not affect any constitutionally protected property rights. These rules will not result in the physical occupancy of property, the physical invasion of property, or the regulatory taking of any property. In fact, these rules allow hunters to exercise privileges that would be otherwise unavailable; and, therefore, reduce restrictions on the use of private and public property.

Federalism Effects

Due to the migratory nature of certain species of birds, the Federal government has been given responsibility over these species by the Migratory Bird Treaty Act. These rules do not have a substantial direct effect on fiscal capacity, change the roles or responsibilities of Federal or State governments, or intrude on State policy or administration. Therefore, in accordance with Executive Order 12612, these regulations do not have significant federalism effects and do not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Government-to-Government Relationship with Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American tribal Governments'' (59 FR 22951) and 512 DM 2, we have evaluated possible effects on Federally recognized Indian tribes and have determined that there are no effects.

Authorship. The primary author of this rule is James R. Kelley, Jr., Office of Migratory Bird Management.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

Accordingly, we are amending part 20, subchapter B, chapter 1 of Title 50 of the Code of Federal Regulations as follows:

PART 20—[AMENDED]

1. The authority citation for part 20 continues to read as follows:

Authority: 16 U.S.C. 703–712 and 16 U.S.C. 742 a–j.

2. Section 20.21 is amended by revising paragraph (j) introductory text, revising paragraphs (j)(2) and (j)(3), and removing paragraph (j)(4) as follows:

20.21 What hunting methods are illegal?

* * * * *

(j) While possessing shot (either in shotshells or as loose shot for muzzleloading) other than steel shot, or bismuth-tin (97 parts bismuth: 3 parts tin with <1 percent residual lead) shot, or tungsten-iron (40 parts tungsten: 60 parts iron with <1 percent residual lead) shot, or tungsten-polymer (95.5 parts tungsten: 4.5 parts Nylon 6 or 11 with <1 percent residual lead) shot, or tungsten-matrix (95.9 parts tungsten: 4.1 parts polymer with <1 percent residual lead) shot, or tin (99.9 percent tin with <1 percent residual lead) shot, or such shot approved as nontoxic by the Director pursuant to procedures set forth in 20.134, provided that:

* * * * *

(2) Tungsten-matrix shot (95.9 parts tungsten: 4.1 parts polymer with <1 percent residual lead) is legal as nontoxic shot for waterfowl and coot hunting for the 1999–2000 hunting season only, and

(3) Tin shot (99.9 percent tin with <1 percent residual lead) is legal as nontoxic shot for waterfowl and coot hunting for the 1999–2000 hunting season only.

Dated: August 12, 1999.

Stephen C. Saunders,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 99–21525 Filed 8–18–99; 8:45 am]

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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–523–6641. This list is also available online at http://www.nara.gov/fedreg.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at http://www.access.gpo.gov/nara/index.html. Some laws may not yet be available.

H.R. 211/P.L. 106–48

To designate the Federal building and United States courthouse located at 920 West Riverside Avenue in Spokane, Washington, as the ''Thomas S. Foley United States Courthouse'', and the plaza at the south entrance of such building and courthouse as the ''Walter F. Horan Plaza''. (Aug. 17, 1999; 113 Stat. 230)

H.R. 1219/P.L. 106–49

Construction Industry Payment Protection Act of 1999 (Aug. 17, 1999; 113 Stat. 231)

H.R. 1568/P.L. 106–50

Veterans Entrepreneurship and Small Business Development Act of 1999 (Aug. 17, 1999; 113 Stat. 233)

H.R. 1664/P.L. 106–51

Emergency Steel Loan Guarantee and Emergency Oil and Gas Guaranteed Loan Act of 1999 (Aug. 17, 1999; 113 Stat. 252)

H.R. 2465/P.L. 106–52

Military Construction Appropriations Act, 2000 (Aug. 17, 1999; 113 Stat. 259)

S. 507/P.L. 106–53

Water Resources Development Act of 1999. (Aug. 17, 1999; 113 Stat. 269)

S. 606/P.L. 106–54

For the relief of Global Exploration and Development Corporation, Kerr-McGee Corporation, and Kerr-McGee Chemical, LLC (successor to Kerr-McGee Chemical Corporation), and for other purposes. (Aug. 17, 1999; 113 Stat. 398)

S. 1546/P.L. 106–55

To amend the International Religious Freedom Act of 1998 to provide additional administrative authorities to the United States Commission on International Religious Freedom, and to make technical corrections to that Act, and for other purposes. (Aug. 17, 1999; 113 Stat. 401)

Last List August 18, 1999

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