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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. 94–NM–151–AD; Amendment 39–9333; AD 95–17–04]

Airworthiness Directives; Jetstream Model ATP Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to all Jetstream Model ATP airplanes, that currently requires revising the Airplane Flight Manual (AFM) to prohibit flight in freezing precipitation conditions. This amendment adds a requirement to install modifications of the engine air intake system. This amendment is prompted by the development of modifications of the engine air intake system intended to permit operation of these airplanes in freezing precipitation conditions. The actions specified by this AD are intended to prevent engine power rollback in flight during freezing precipitation conditions.

DATES: Effective September 13, 1995.

The incorporation by reference of certain publications, as listed in the regulations, is approved by the Director of the **Federal Register** as of September 13, 1995.

The incorporation by reference of certain other publications listed in the regulations was approved previously by the Director of the **Federal Register** as of June 15, 1994 (59 FR 25290, May 16, 1994).

ADDRESSES: The service information referenced in this AD may be obtained from Jetstream Aircraft, Inc., P.O. Box 16029, Dulles International Airport, Washington, DC 20041–6029. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the **Federal Register**, 800 North Capitol Street NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: William Schroeder, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone (206) 227–2148; fax (206) 227–1320.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 94–08–01, amendment 39–8872 (59 FR 25290, May 16, 1994), which is applicable to all Jetstream Model ATP airplanes, was published in the **Federal Register** on December 29, 1994 (59 FR 67243). The action proposed to require certain actions that were previously optional terminating actions. The action also proposed to provide several new optional terminating actions. Additionally, the action proposed to revise the applicability of the rule.

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

The commenter supports the proposed rule.

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

The FAA estimates that 10 airplanes of U.S. registry will be affected by this AD, that it will take approximately 150 work hours per airplane to accomplish the required actions, and that the average labor rate is $60 per work hour. Required parts will be provided by the manufacturer at no cost to the operator. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $90,000, or $9,000 per airplane.

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–8872 (59 FR 25290, May 16, 1994), and by adding a new airworthiness directive (AD), amendment 39–9333, to read as follows:

95–17–04 Jetstream Aircraft Limited (Formerly British Aerospace Commercial Aircraft Limited): Amendment 39–9333. Docket 94–NM–151–AD. Supersedes AD 94–08–01, Amendment 39–8872.

Applicability: Model ATP airplanes, as listed in Jetstream Service Bulletin ATP 54–

13–35274B, Revision 2, dated August 18, 1994, certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent loss of multiple engine power during flight in freezing precipitation, accomplish the following:

(a) Within 30 days after June 15, 1994 (the effective date of AD 94–08–01, amendment 39–8872), revise the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to include the following statement. This may be accomplished by inserting a copy of this AD in the AFM.

''Flight is prohibited into forecast or reported freezing precipitation conditions where the outside air temperature is between +5°C and −5°C.''

(b) Within 72 days after the effective date of this AD, accomplish the actions specified in paragraphs (b)(1), (b)(2), (b)(3), (b)(4), (b)(5), and (b)(6), which will constitute terminating action for the AFM revision required by paragraph (a) of this AD. Once these actions are completed, the AFM revision required by paragraph (a) may be removed.

(1) Revise the Limitations Section and the Normal Procedures Section of the FAA-approved AFM, to include the information specified in Temporary Revision T/33, Issue 1, dated November 1, 1993, and Temporary Revision T/38, Issue 1, dated February 16, 1994, which introduce procedures for operation in icing conditions, as specified in the temporary revision; and operate the airplane in accordance with those limitations and procedures.

Note 2: This may be accomplished by inserting copies of Temporary Revision T/33 and T/38 in the AFM. When these temporary revisions have been incorporated into general revisions of the AFM, the general revisions may be inserted in the AFM, provided the information contained in the general revision is identical to that specified in Temporary Revision T/33 and T/38.

(2) Incorporate a revision into the FAA-approved maintenance program that provides for replacement of engine igniter plugs at the intervals specified in Jetstream Service Bulletin ATP–80–06, Revision 1, dated October 22, 1993, or Revision 2, dated October 16, 1994. Initial replacement of an engine igniter plug with a new plug shall be accomplished prior to the accumulation of 200 total hours time-in-service on the engine igniter plug, or within 50 hours time-in-service after incorporating the maintenance program revision, whichever occurs later.

(3) Install an eductor plate over the exhaust port of the engine air intake system in accordance with Jetstream Service Bulletin ATP–54–12–35274A, dated September 28, 1993, or Revision 1, dated December 15, 1993. Any eductor plate installed in accordance with the original issue of the service bulletin must be inspected for any aperture profile mismatch, in accordance with paragraph 2., Part B., of the Accomplishment Instructions of Revision 1 of the service bulletin. If any mismatch is found that exceeds the limit specified in that service bulletin, prior to further flight, correct the discrepancy in accordance with paragraph 2., Part C, of Revision 1 of the service bulletin.

(4) For airplanes having constructor's numbers 2007, 2010 through 2016 inclusive, 2020 through 2022 inclusive, 2028, 2029, 2032, 2034 through 2037 inclusive, 2041 through 2044 inclusive, 2051, 2053, and 2056: Install engine air inlet ducts that incorporate electrical de-ice heaters with increased power and area, and perform associated electrical system changes, in accordance with the Accomplishment Instructions, in Jetstream Service Bulletin ATP–54–13–35274B, dated October 9, 1993, or Parts A through F of Revision 1, dated July 8, 1994, or Revision 2, dated August 18, 1994.

(5) For airplanes having constructor's numbers 2002 through 2006 inclusive, 2008, 2009, 2017 through 2019 inclusive, 2023 through 2027 inclusive, 2030, 2031, 2033, 2038 through 2040 inclusive, 2045 through 2050 inclusive, 2052, 2054 through 2055 inclusive, and 2057 through 2063 inclusive: Install engine air inlet ducts that incorporate electrical de-ice heaters with increased power, in accordance with the Accomplishment Instructions, Part G, of Jetstream Service Bulletin ATP–54–13–35274B, Revision 2, dated August 18, 1994.

Note 3: Installation of engine air inlet ducts in accordance with Jetstream Service Bulletin ATP–54–15–35274E, dated July 27, 1994, is considered acceptable for compliance with either paragraph (b)(4) or (b)(5) of this AD.

(6) Revise the FAA-approved maintenance program to include repetitive visual inspections for damage of the heater mats at intervals not to exceed 50 hours time-in-service, in accordance with Jetstream Service Bulletin ATP–54–14, dated October 14, 1993; and, if any damage is found, prior to further flight, replace the engine air intake in accordance with the service bulletin.

(c) The following installations on both engines constitute terminating action for the repetitive replacement of the engine igniter plugs required by paragraph (b)(2) of this AD:

(1) Installation of new de-ice timers in accordance with Jetstream Service Bulletin ATP–30–39–30146A, dated July 29, 1994,

(2) Wiring changes to incorporate automatic duct heat when engine air intake lip heat is selected ''on,'' in accordance with Jetstream Service Bulletin ATP–30–37–30143A, dated August 1, 1994, or Revision 1, dated September 5, 1994, and

(3) Installation of an engine automatic ignition system in accordance with Jetstream Service Bulletin ATP–80–7–30141A, Revision 2, dated November 4, 1994; and an associated revision of the FAA-approved Airplane Flight Manual (AFM) by incorporating the information contained in Temporary Revision T/42, Issue 1, dated August 12, 1994.

(d) For airplanes on which the engine air intake (Modification 35274E) has been installed in accordance with Jetstream Service Bulletin ATP–54–15–35274E, dated July 27, 1994: The installation of engine duct de-ice overheat protection (Modification 35274D) in accordance with Jetstream Service Bulletin ATP–30–44–35274D, dated August 12, 1994, constitutes terminating action for the repetitive inspections required by paragraph (b)(6) of this AD.

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

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

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

(g) The actions shall be done in accordance with the following documents, as applicable, which contain the specified effective pages:

Service bulletin referenced and date	Page No.	Revision level shown on page	Date shown on page
Temporary Revision T/42	1–18	1	August 12, 1994.
Issue 1, August 12, 1994	3–7	Original	March 2, 1993.
ATP 30–37–30143A, August 1, 1994	1–15	Original	August 1, 1994.

Service bulletin referenced and date	Page No.	Revision level shown on page	Date shown on page
ATP 30–37–30143A, Revision 1, September 5, 1994.	1–3, 5–10, 14–17	1	September 5, 1994.
	4, 11–13	Original	August 1, 1994.
ATP–30–39–30146A, July 29, 1994	1–7	Original	July 29, 1994.
ATP–30–44–35274D, August 12, 1994	1–56	Original	August 12, 1994.
ATP–54–13–35274B, Revision 1, July 8, 1994	1–45	1	July 8, 1994.
ATP–54–13–35274B, Revision 2, August 18, 1994	1–4, 9, 10	2	August 18, 1994.
	5–8, 11–45	1	July 8, 1994.
ATP–80–06, Revision 2, October 16, 1994	1–6	2	October 16, 1994.
ATP–80–7–30141A, Revision 2, November 4, 1994.	1, 3, 5–8, 11, 14, 17, 18, 20–28, 36, 38, 45, 46, 51–55.	2	November 4, 1994.
	2, 4, 9, 10, 12, 13, 15, 16, 19, 29–35, 37, 39–44, 47–50.	Original	August 1, 1994.

This incorporation by reference of certain publications listed in the regulations was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The incorporation by reference of certain other publications listed in the regulations was approved previously by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 as of June 15, 1994 (59 FR 29290, May 16, 1994). Copies may be obtained from Jetstream Aircraft, Inc., P.O. Box 16029, Dulles International Airport, Washington, DC 20041–6029. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on September 13, 1995.

Issued in Renton, Washington, on July 31, 1995.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–19231 Filed 8–11–95; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 39

[Docket No. 94–NM–14–AD; Amendment 39–9330; AD 95–17–01]

Airworthiness Directives; Boeing Model 707 and 720 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Boeing Model 707 and 720 series airplanes, that currently requires repetitive visual and dye penetrant inspections to detect cracks in areas of the upper forward skin panels of the wing center section, and repair, if necessary. It also provides an optional terminating modification for the repetitive inspections. This amendment requires repetitive visual and eddy current inspections to detect cracks in areas of the upper forward skin panels of the wing center section, and repair, if necessary. This amendment is prompted by reports indicating that the inspections required by the existing AD are not effective in detecting fatigue cracks in a timely manner. The actions specified by this AD are intended to prevent fatigue cracking and subsequent failure of the upper forward skin panels of the wing center section.

DATES: Effective on September 13, 1995.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of September 13, 1995.

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

FOR FURTHER INFORMATION CONTACT: Phil Forde, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington, 98055–4056; telephone (206) 227–2771; fax (206) 227–1181.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add an airworthiness directive (AD), applicable to certain Boeing Model 707 and 720 series airplanes, was published as a supplemental notice of proposed rulemaking (NPRM) in the **Federal Register** on February 7, 1995 (60 FR 7143). That supplemental NPRM proposed to supersede AD 68–18–03, amendment 39–2056. That AD currently requires repetitive visual and dye penetrant inspections to detect cracks on the upper forward skin panels of the wing center section, and repair, if necessary. It also provides an optional terminating modification for the repetitive inspections. The supplemental NPRM proposed to require repetitive visual and eddy current inspections to detect cracks on the upper forward skin panels of the wing center section, and repair, if necessary.

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

The commenter requests that paragraph (e) of the proposal be revised to allow that the terminating action specified in that paragraph be accomplished in accordance with procedures contained in revisions prior to Revision 6 of Boeing Service Bulletin 2590, provided that, in addition to the installation of reinforcing stiffeners, the forward skin panel is replaced. The commenter indicates that the modifications described in these earlier revisions of the service bulletin are identical to those specified in Revisions 6 and subsequent. The commenter adds that the ''aging fleet document'' (Boeing Document D6–54496), which addresses the affected airplanes, specifies that modifications accomplished in accordance with the original issue through Revision 8 of Boeing Service Bulletin 2590 are considered to be terminating action, provided that new forward skin panels are installed. The commenter states that the inconsistency

between the proposal and the ''aging fleet document'' in this regard has caused confusion among some operators as to whether airplanes modified in accordance with earlier revisions of the service bulletin are considered to be in compliance with the proposed AD.

The FAA concurs partially. The FAA has re-examined the earlier revisions of the service bulletin, and has determined that the original issue and Revisions 1 through 3 of the service bulletin were issued as telegraphic documents. These revisions do not adequately address procedures for accomplishing the terminating modifications in sufficient detail. Therefore, the FAA does not consider these revisions to be acceptable for accomplishment of the terminating modification specified in this AD. However, Revision 4 does provide adequate procedures for accomplishing the terminating modification for Model 720 series airplanes, provided that the forward skin panel also is replaced in accordance with the service bulletin. In addition, Revision 5 contains adequate information for accomplishment of the terminating modification for both Model 707 and 720 series airplanes, provided that the forward skin panel also is replaced in accordance with the service bulletin. These determinations have been specified in paragraphs (e) and (f) of the final rule for Models 707 and 720 series airplanes, respectively.

Certain service bulletin titles were referenced incorrectly in NOTE 2 and paragraphs (c)(1), (c)(2), and (c)(3) of the supplemental NPRM as ''Boeing Master Inspection Service Bulletins.'' The appropriate titles for these service documents are ''Boeing Service Bulletins.'' The FAA has revised the note and those paragraphs of the final rule accordingly. In addition, the FAA has added references to specific page numbers of those service bulletins for the convenience of operators.

In addition, paragraph (e) of the supplemental NPRM did not specify that Revision 6 of Boeing Service Bulletin 2590 was issued as an alert service bulletin. The final rule has been revised accordingly.

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

There are approximately 416 Model 707 and 720 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 82 airplanes of U.S. registry will be affected by this AD, that it will take approximately 32 work hours per airplane to accomplish the required actions, and that the average labor rate is $60 per work hour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $157,440, or $1,920 per airplane, per inspection cycle.

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

Should an operator elect to accomplish the optional terminating action that is provided by this AD action, it will take approximately 1,250 work hours to accomplish it, at an average labor rate of $60 per work hour. The cost of required parts is approximately $45,000 per airplane. Based on these figures, the total cost impact of the optional terminating action is estimated to be $120,000 per airplane.

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40101, 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–2056, and by adding a new airworthiness directive (AD), amendment 39– , to read as follows:

95–17–01 Boeing: Amendment 39–9330. Docket 94–NM–14–AD. Supersedes AD 68–18–03, Amendment 39–2056.

Applicability: Model 707 and 720 series airplanes; as listed in Boeing Service Bulletin 2590, Revision 11, dated December 12, 1991; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent fatigue cracking and subsequent failure of the upper forward skin panels of the wing center section, accomplish the following:

(a) For Model 707–100, –200, –300, –300B, –300C, and –400 series airplanes on which no bulb angle stiffeners have been installed in accordance with Boeing Service Bulletin 2590: Perform a visual inspection and an eddy current inspection to detect cracks in the areas of the upper forward skin of the wing center section specified in paragraphs b. and f.(1) of Part I of the Accomplishment Instructions of Boeing Service Bulletin 2590, Revision 8, dated June 2, 1972; Revision 9, dated March 14, 1975; Revision 10, dated January 31, 1991; or Revision 11, dated December 12, 1991. Perform the inspections at the time specified in paragraph (a)(1) or (a)(2) of this AD, as applicable, in accordance with the procedures specified in the service bulletin. Repeat these inspections thereafter at intervals not to exceed 450 landings.

(1) For Model 707–300, –300B, –300C, and –400 series airplanes: Inspect at the later of the times specified in paragraphs (a)(1)(i) and (a)(1)(ii) of this AD.

(i) Prior to the accumulation of 6,000 total landings; or

(ii) Within 500 landings or 18 months after the effective date of this AD, whichever occurs first.

(2) For Model 707–100 and –200 series airplanes: Inspect at the later of the times specified in paragraphs (a)(2)(i) and (a)(2)(ii) of this AD.

(i) Prior to the accumulation of 6,400 total landings; or

(ii) Within 500 landings or 18 months after the effective date of this AD, whichever occurs first.

(b) For Model 720 and 720B series airplanes on which no bulb angle stiffeners have been installed in accordance with Boeing Service Bulletin 2590: Perform a visual inspection and an eddy current inspection to detect cracks in the area of the upper forward skin of the wing center section specified in paragraph b. of Part I of the Accomplishment Instructions of Boeing Service Bulletin 2590, Revision 8, dated June 2, 1972; Revision 9, dated March 14, 1975; Revision 10, dated January 31, 1991; or Revision 11, dated December 12, 1991. Perform the inspections at the later of the times specified in paragraphs (b)(1) and (b)(2) of this AD, in accordance with the procedures specified in the service bulletin. Repeat these inspections thereafter at intervals not to exceed 450 landings.

(1) Prior to the accumulation of 4,000 total landings; or

(2) Within 500 landings or 18 months after the effective date of this AD, whichever occurs first.

(c) For Model 720 and 720B, and 707–100, –200, –300, –300B, –300C, and –400 series airplanes on which bulb angle stiffeners have been installed, but on which the wing skin has not been replaced, in accordance with Boeing Service Bulletin 2590: Accomplish the inspections required by paragraph (c)(1), (c)(2), or (c)(3) of this AD, as applicable, in accordance with Boeing Service Bulletin 2590, Revision 11, dated December 12, 1991. Repeat these inspections thereafter at intervals not to exceed 1,000 landings.

Note 2: Revision 11 of Boeing Service Bulletin 2590 is part of Boeing Service Bulletins 3484 (for Model 707–100 and –200 series airplanes), 3485 (for Model 720 and 720B series airplanes), and 3486 (for Model 707–300, –300B, –300C, and –400 series airplanes), all dated December 12, 1991. Boeing Service Bulletin 2590 references these service bulletins as additional sources of service information concerning accomplishment of the inspections required by paragraph (c) of this AD.

(1) For Model 720 and 720B series airplanes: Perform a visual and an eddy current inspection to detect cracks in the areas of the upper forward skin of the wing center section specified on pages 34 and 35 of Boeing Service Bulletin 3485, dated December 12, 1991, at the later of the times specified in paragraphs (c)(1)(i) and (c)(1)(ii) of this AD.

(i) Prior to the accumulation of 2,200 landings after installation of the bulb angle stiffeners; or

(ii) Within 500 landings or 18 months after the effective date of this AD, whichever occurs first.

(2) For Model 707–300, –300B, –300C, and –400 series airplanes: Perform a visual and an eddy current inspection to detect cracks in the areas of the upper forward skin of the wing center section specified on page 55 of Boeing Service Bulletin 3486, dated December 12, 1991, at the later of the times specified in paragraphs (c)(2)(i) and (c)(2)(ii) of this AD.

(i) Prior to the accumulation of 2,200 landings after installation of the bulb angle stiffeners; or

(ii) Within 500 landings or 18 months after the effective date of this AD, whichever occurs first.

(3) For Model 707–100 and –200 series airplanes: Perform a visual and an eddy current inspection to detect cracks in the areas of the upper forward skin of the wing center section specified on pages 37 and 38 of Boeing Service Bulletin 3484, dated December 12, 1991, at the later of the times specified in paragraphs (c)(3)(i) and (c)(3)(ii) of this AD.

(i) Prior to the accumulation of 2,200 landings after installation of the bulb angle stiffeners; or

(ii) Within 500 landings or 18 months after the effective date of this AD, whichever occurs first.

(d) If any crack is found during any inspection required by paragraph (a), (b), or (c) of this AD, prior to further flight, repair in accordance with Part II of the Accomplishment Instructions of Boeing Service Bulletin 2590, Revision 7, dated September 22, 1969; Revision 8, dated June 2, 1972; Revision 9, dated March 14, 1975; Revision 10, dated January 31, 1991; or Revision 11, dated December 12, 1991.

(e) For Model 707 series airplanes: Accomplishment of the ''Reinforcing Stiffener Installation and Skin Panel Replacement'' in accordance with Part III of the Accomplishment Instructions of Boeing Alert Service Bulletin 2590, Revision 6, dated July 8, 1968; Boeing Service Bulletin 2590, Revision 7, dated September 22, 1969, Revision 8, dated June 2, 1972, Revision 9, dated March 14, 1975, Revision 10, dated January 31, 1991, or Revision 11, dated December 12, 1991; constitutes terminating action for the inspections required by paragraphs (a), (b), and (c) of this AD. Accomplishment of the reinforcement and replacement in accordance with Boeing Alert Service Bulletin 2590, Revision 5, dated September 20, 1967, also is considered acceptable for compliance with paragraph (e) of this AD provided that the forward skin panel also is replaced in accordance with that service bulletin.

(f) For Model 720 series airplanes: Accomplishment of the ''Reinforcing Stiffener Installation and Skin Panel Replacement'' in accordance with Part III of the Accomplishment Instructions of Boeing Alert Service Bulletin 2590, Revision 6, dated July 8, 1968; Boeing Service Bulletin 2590, Revision 7, dated September 22, 1969, Revision 8, dated June 2, 1972, Revision 9, dated March 14, 1975, Revision 10, dated January 31, 1991, or Revision 11, dated December 12, 1991; constitutes terminating action for the inspections required by paragraphs (a), (b), and (c) of this AD. Accomplishment of the reinforcement and replacement in accordance with Boeing Alert Service Bulletin 2590, Revision 4, dated May 26, 1967, or Revision 5, dated September 20, 1967, also is considered acceptable for compliance with paragraph (f) of this AD provided that the forward skin panel also is replaced in accordance with that service bulletin.

(g) 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 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(h) 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.

(i) The actions shall be done in accordance with the following service documents:

Boeing Alert Service Bulletin 2590, Revision 4, dated May 26, 1967;

Boeing Alert Service Bulletin 2590, Revision 5, dated September 20, 1967;

Boeing Alert Service Bulletin 2590, Revision 6, dated July 8, 1968;

Boeing Service Bulletin 2590, Revision 7, dated September 22, 1969;

Boeing Service Bulletin 2590, Revision 8, dated June 2, 1972;

Boeing Service Bulletin 2590, Revision 9, dated March 14, 1975;

Boeing Service Bulletin 2590, Revision 10, dated January 31, 1991;

Boeing Service Bulletin 2590, Revision 11, dated December 12, 1991;

Pages 37 and 38 of Boeing Service Bulletin 3484, dated December 12, 1991;

Pages 34 and 35 of Boeing Service Bulletin 3485, dated December 12, 1991; and

Pages 55 and 56 of Boeing Service Bulletin 3486, dated December 12, 1991.

Boeing Alert Service Bulletin 2590, Revision 6, dated July 8, 1968, contains the following specified effective pages:

Page No.	Revision level shown on page	Date shown on page
1, 3–5, 7, 9, 10, 14, 16	6	July 8, 1968.
2, 6, 8, 11–13, 15	5	September 20, 1967.

This incorporation by reference was approved by the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the **Federal Register**, 800 North Capitol Street, NW., suite 700, Washington, DC.

(j) This amendment becomes effective on September 13, 1995.

Issued in Renton, Washington, on July 28, 1995.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–19120 Filed 8–11–95; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 71

[Docket No. 95–ANE–24]

Revocation of Class D and Class E Airspace; Limestone, ME

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment revokes the Class D and Class E airspace areas established at the former Loring Air Force Base, and amends the Class E airspace at the Northern Maine Regional Airport at Presque Isle, ME, to delete that portion of that airspace in the vicinity of Loring AFB. This action is necessary since Loring AFB is no longer in operation, all standard instrument approach procedures to Loring AFB have been canceled, and the air traffic control tower at Loring AFB is closed.

EFFECTIVE DATE: 0901 UTC, September 14, 1995.

FOR FURTHER INFORMATION CONTACT: Joseph A. Bellabona, System Management Branch, ANE–530, Federal Aviation Administration, 12 New England Executive Park, Burlington, MA 01803–5299; telephone: (617) 238–7536; fax: (617) 238–7596.

SUPPLEMENTARY INFORMATION:

History

On May 17, 1995, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by removing the Class D and Class E airspace areas established at the former Loring Air Force Base (AFB) in Limestone, ME, and by revising the Class E airspace area established in the vicinity of the Northern Maine Regional Airport at Presque Isle, ME. That action was prompted by the cancellation of all standard instrument approach procedures (SIAP's) to the former Loring AFB, which followed the closing of the control tower at Loring AFB.

Interested parties were invited to participate in this rule making proceeding by submitting written comments on the proposal to the FAA. No comments were received. Class D and Class E airspace areas are published in FAA Order 7400.9B, dated July 18, 1994, and effective September 16, 1994, which is incorporated by reference in 14 CFR 71.1. Class D areas appear in paragraph 5000 of FAA Order 7400.9B, and Class E areas designated as extensions to Class D areas appear in paragraph 6004 and Class E areas extending upward from 700 feet or more above the surface of the earth appear in paragraph 6005. The Class D and Class E airspace designations in this document would be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) removes the Limestone, ME Class D area and the Limestone, ME Class E area, and revises the Presque Isle, ME Class E area by deleting the portion of that airspace in the vicinity of the former Loring AFB.

The FAA has determined that this rule involves only established body of technical regulations for which frequent and routine amendments are necessary to keep these regulations operationally current. It therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated economic cost will be so minimal. Since this is a rountine matter that will only affect air traffic procedure and air navigation, the FAA certifies that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

If consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority. 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR. 1959–1963, Comp., P. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9B, Airspace Designations and Reporting Points, dated July 18, 1994, and effective September 16, 1994, is amended as follows:

Paragraph 5000 General

* * * * *

ANE ME D Limestone, ME [Removed]

* * * * *

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D Surface Area

* * * * *

ANE ME E4 Limestone, ME [Removed]

* * * * *

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth

* * * * *

ANE CT E5 Preque Isle, ME [Revised]

Northern Maine Regional Airport at Presque Isle, ME
(Lat. 46°41′20″ N, long. 62°02′41″ W)
Presque Isle VORTAC
(Lat. 46°46′27″ N, long. 68°05′40″ W)
EXCAL LOM
(Lat. 46°36′37″ N, long. 68°01′08″ W)
Caribou Municipal Airport, ME
(Lat. 46°52′17″ N, long. 68°01′04″ W)

That airspace extending upward from 700 feet above the surface within an 11-mile radius of Northern Maine Regional Airport at Presque Isle, and within 3 miles on each side of the EXCAL LOM 165° bearing extending

from the 11-mile radius to 9.2 miles south of the EXCAL LOM, and within 4 miles east and 8 miles west of the Presque Isle VORTAC 340° radial extending from the 11-mile radius to 16 miles northwest of the Presque Isle VORTAC, and within an 8.5-mile radius of Caribou Municipal Airport, ME; excluding that airspace outside of the United States.

* * * * *

Issued in Burlington, MA, on August 4, 1995.

John J. Boyce,

Acting Manager, Air Traffic Division, New England Region.

[FR Doc. 95–19906 Filed 8–11–95; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 71

[Docket No. 95–ANE–23]

Establishment of Class E Airspace; Portland, ME

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment will establish Class E airspace in the vicinity of the Portland International Jetport, Portland, ME, that coincides with the hours that the associated radar approach control facility is not in operation. This action does not change the designated boundaries or altitudes of the Portland Class C airspace, but only establishes the necessary Class E airspace to provide sufficient controlled airspace for those aircraft operating under instrument flight rules (IFR) in the vicinity of the Portland International Jetport when the Portland Air Traffic Control Tower (ATCT) and Terminal Radar Control Approach Facility (TRACON) are not in operation.

EFFECTIVE DATE: 0901 UTC, September 14, 1995.

FOR FURTHER INFORMATION CONTACT: Joseph A. Bellabona, System Management Branch, ANE–530, Federal Aviation Administration, 12 New England Executive Park, Burlington, MA 01803–5299; telephone: (617) 238–7536; fax: (617) 238–7596.

SUPPLEMENTARY INFORMATION:

History

On May 17, 1995, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by establishing Class E airspace in the vicinity of the Portland International Jetport, Portland, ME. That action was prompted by the need to establish the necessary Class E airspace to provide sufficient controlled airspace for those aircraft operating under instrument flight rules (IFR) in the vicinity of the Portland International Jetport when the Portland Air Traffic Control Tower (ATCT) and Terminal Radar Control Approach Facility (TRACON) are not in operation. Since the Portland Class C airspace is predicated on an operational ATCT and serviced by a TRACON, Class E airspace must be defined for the hours when that facility is not in operation. This action does not change the designated boundaries or altitudes of the Portland Class C airspace. The hours of operation for the Portland ATCT are published by a Notice to Airman (NOTAM) and thereafter in the Airport/Facility Directory.

Interested parties were invited to participate in this rule making proceeding by submitting written comments on the proposal to the FAA. No comments were received. Class E airspace areas designated as a surface area for an airport are published in Paragraph 6002 of FAA Order 7400.9B, dated July 18, 1994, and effective September 16, 1994, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation in this document would be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) establishes Class E airspace at the Portland International Jetport, Portland, ME.

The FAA has determined that this rule involves only an established body of technical regulations for which frequent and routine amendments are necessary to keep these regulations operationally current. It therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866 (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated economic cost will be so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, the FAA certifies that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a) 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963, Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9B, Airspace Designations and Reporting Points, dated July 18, 1994, and effective September 16, 1994, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as a Surface Area for an Airport

* * * * *

ANE ME E2 Portland International Jetport, ME [New]

Portland International Jetport, ME
(Lat. 43°38′46″ N, long. 70°18′31″ W)

Within a 5-mile radius of the Portland International Jetport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airman. The effective dates and times will thereafter be continuously published in the Airport/Facility Directory.

Issued in Burlington, MA, 0n August 4, 1995.

John J. Boyce,

Acting Manager, Air Traffic Division, New England Region.

[FR Doc. 95–19907 Filed 8–11–95; 8:45 am]

BILLING CODE 4910–13–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1117

Reporting Choking Incidents to the Consumer Product Safety Commission Pursuant to the Child Safety Protection Act; Revision to Interpretative Rule

AGENCY: Consumer Product Safety Commission.

ACTION: Revision to final interpretative rule.

SUMMARY: The Child Safety Protection Act (''CSPA'') requires manufacturers, distributors, retailers, and importers of marbles, small balls, latex balloons, and toys or games that contain such items or other small parts, to report to the Commission when they learn of choking incidents involving such products. On February 27, 1995, the Commission issued a rule interpreting the reporting requirements of the CSPA, but left open the question of whether the reporting requirement applies to toys or games that are exempt from the Commission's

small parts banning rule (16 CFR Part 1501). This revision states that the reporting requirements apply to toys and games that would otherwise be exempt from the Commission's small parts regulation. The revision also clarifies that firms must report any time a child chokes on a small part from a toy or game regardless of whether the part was a small part at the time the product was distributed or sold.

DATES: This regulation becomes effective on September 13, 1995.

FOR FURTHER INFORMATION CONTACT: Eric L. Stone, Office of Compliance and Enforcement, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814 (Mailing address: Washington, D.C. 20207), telephone (301) 504–0626 extension 1350.

SUPPLEMENTARY INFORMATION:

A. Background

Section 102 of the Child Safety Protection Act of 1994 (Public Law 103–267, 108 Stat. 722, June 16, 1994) requires, inter alia, that each manufacturer, distributor, retailer and importer of a toy or game that contains a small part report to the Commission information that reasonably supports the conclusion that an incident occurred in which a child choked on the small part and died, suffered serious injury, ceased breathing for any length of time, or was treated by a medical professional. On February 27, 1995, the Commission published a final interpretative rule defining several terms and resolving ambiguities and uncertainties in the statutory reporting scheme. 60 FR 10490. The Commission left unresolved one issue raised by commenters. Those commenters had questioned whether the reporting requirement applied to toys and games that are exempt from the Commission's small parts banning rule. 16 CFR Part 1501.

A subsequent industry inquiry also indicated some confusion over the definition of the term ''small part'' in the regulation. The Commission has decided to clarify that definition.[1]

1. Products Exempt From the Small Parts Regulation

Several industry commenters originally suggested that the Commission exempt from the choking hazard reporting requirement any products that are exempt from the small parts banning regulation (see 16 CFR 1501.3). The banning regulation, which applies to toys and other articles intended for children under 3 years of age, exempted items such as balloons, books, writing materials, and certain children's grooming, hygiene, and feeding items because the Commission believed that the functional benefits of these products outweighed the risk of injury they presented.

The Commission believes that Congress enacted the reporting requirements of the CSPA to assure that the Commission receives as much information as possible about serious choking incidents. Only then, can the Commission know whether some remedial action is necessary to protect children. Absent compelling reasons to do so, the Commission believes it should not carve out exceptions to the reporting obligations imposed by Congress.

Congress required firms to report choking incidents involving small parts from toys and games. Congress did not limit this reporting obligation to products subject to the Commission's small parts banning regulation (16 CFR 1501). The Commission believes that no persuasive policy arguments support limiting the requirement imposed by Congress. Unlike a ban, the reporting requirement does not interfere with the sale of the exempt product or place an extraordinary burden on the reporting firm. The scope of the reporting obligation is limited, the report is protected from public disclosure, and the information may not be used as an admission against the firm. Therefore, the Commission sees no reason to limit reporting to products that would be subject to 16 CFR Part 1501.

2. Definition of ''Small Part''

The CSPA requires reporting when a child chokes on a small part contained in a toy or game. The final regulation defines a small part as any object which, when tested in accordance with the procedures of 16 CFR 1501.4(a) and 1501.4(b)(1) fits entirely within the cylinder shown in Figure 1 appended to 16 CFR Part 1501. When the Commission issued rules interpreting the CSPA reporting requirements, the Commission intended that firms report to the Commission if the part involved in the choking incident fit within the small parts test cylinder. The Commission expected firms to report choking incidents involving parts that broke off a toy or game as well as those involving parts that were small parts at the time the toy or game was distributed or sold.

Although firms who are reporting under this provision seem to understand the Commission's rule, one firm has suggested it is not clear. That firm thought the reporting provision should only apply to parts that are independent small parts at the time the toy or game is sold. It suggests that the phrase ''contained in such toy or game'' in section 102 limited the obligation to distinct small parts contained in the toy or game at the time of distribution or sale of the toy or game.

The focus of the choking hazard reporting provision is upon the choking incident. If a small part causes a choking incident a manufacturer, importer, distributor, or retailer is obligated to report if that part was contained in its toy or game. The phrase ''contained in'' is an indicator of the origin of the part. The part was contained in the toy or game whether it was a separate small part at the time of distribution, or a component or piece of a toy that broke off during play. Limiting the reporting obligation to items that were small parts at the time of distribution would shift the focus away from reporting of choking incidents. Further, it would only capture a fraction of the choking incidents that occur each year involving parts of toys and games.

In administering the small parts banning regulation, the Commission has seen that the great majority of violations arise because small parts detach from toys as a result of use or abuse. Excluding such parts from the reporting requirements could result in significant violations of the small parts regulation being undetected and uncorrected, even though those violations resulted in death or serious injury—the precise consequences that the reporting requirements were enacted to address.

Accordingly, to resolve the confusion over the scope of the term ''small part,'' the Commission is revising the interpretative rule to clarify that the inquiry as to whether an object involved in a choking incident is a small part should focus only on whether that object fits entirely within the small parts testing cylinder. How the object came to be a small part is irrelevant for the purposes of reporting, although such information may certainly be relevant in determining whether any remedial measures are appropriate.

C. Notice

Because this is an interpretative rule, the Commission is not required to issue a notice of proposed rulemaking. 5 U.S.C. 553(b)(A). Nevertheless, the Commission did publish a notice of proposed rulemaking (''NPR'') concerning the reporting requirements under the CSPA on July 1, 1994. 59 FR

[1] On both of these issues, Commissioner Mary Gall dissented from the Commission's decision. A copy of her statement and those of the other Commissioners may be found in the Commission's Office of the Secretary.

33927. The scope of the NPR covered the issues of reporting for exempt products and for small parts that detach from a toy or game after purchase. Thus, no additional notice is necessary.

D. Impact on Small Businesses

In accordance with section 3(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commission certifies that this regulation will not have a significant economic impact upon a substantial number of small entities if issued on a final basis. Any obligations imposed upon such entities arise under the express provisions of section 102 of the Child Protection Safety Act, Pub. L. No. 103–267, June 17, 1994. This regulation simply revises a narrow aspect of the Commission's interpretation of the obligations imposed by that law. The regulation itself will not have a significant economic impact on small businesses, either beneficial or negative, beyond that which results from the statutory provisions.

E. Environmental Considerations

This revision falls within the provisions of 16 CFR 1021.5(c), which designates categories of actions conducted by the Consumer Product Safety Commission that normally have little or no potential for affecting the human environment. The Commission does not believe that the rule contains any unusual aspects which may produce effects on the human environment, nor can the Commission foresee any circumstance in which the rule issued below may produce such effects. For this reason, neither an environmental assessment nor an environmental impact statement is required.

F. Effective Date

This regulation will become effective 30 days after publication of the final regulation in the **Federal Register**.

List of Subjects in 16 CFR Part 1117

Administrative practice and procedure, Business and industry, Consumer protection, Toy safety, Reporting and recordkeeping requirements, and Small parts.

Conclusion

Therefore, pursuant to the authority of the Child Safety Protection Act [Pub. L. No. 103–267), section 16(b) of the CPSA (15 U.S.C. 2065(b)) and 5 U.S.C. 553, the CPSC amends Part 1117, Chapter II, Subchapter B of Title 16 of the Code of Federal Regulations as follows:

PART 1117—REPORTING OF CHOKING INCIDENTS INVOLVING MARBLES, SMALL BALLS, LATEX BALLOONS AND OTHER SMALL PARTS

1. The authority for Part 1117 continues to read as follows:

Authority: Section 102 of the Child Safety Protection Act (Pub. L. No. 103–267) section 16(b), 15 U.S.C. 2065(b) and 5 U.S.C. 553.

2. Section 1117.2(a) is revised to read as follows:

§ 1117.2 Definitions.

(a) *Small part* means any part, component, or piece of a toy or game, which, when tested in accordance with the procedures in 16 CFR 1501.4(a) and 1501.4(b)(1), fits entirely within the cylinder shown in Figure 1 appended to 16 CFR 1501.

§ 1117.2 [Amended]

3. Section 1117.2 is amended by adding a new paragraph (h) to read as follows:

* * * * *

(h) *Toy or game* includes any toy or game, including those exempt under 16 CFR 1501.3 from the small parts banning provisions of 16 CFR 1500.18(a)(9).

Dated: August 3, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 95–19628 Filed 8–11–95; 8:45 am]

BILLING CODE 6355–01–P

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16 CFR Part 1500

Labeling Certain Toys and Games Pursuant to the Child Safety Protection Act; Revision to final rule

AGENCY: Consumer Product Safety Commission.

ACTION: Revision to final rule.

SUMMARY: The Child Safety Protection Act of 1994 (''CSPA'') requires, in part, toys or games that are intended for children between three and six years of age and contain small parts to bear specific precautionary labels. On February 27, 1995, the Commission issued a final rule interpreting certain provisions of the CSPA. As the preamble to the final rule noted, the Commission did not then resolve the issue of labeling for products exempt from the Commission's existing small parts rule. This revision clarifies that the labeling requirements do not apply to toys and games intended for children three to six years of age that would otherwise be exempt from the banning provisions of the Commission's small parts regulation if they were intended for children under three.

DATES: This regulation becomes effective on August 14, 1995.

FOR FURTHER INFORMATION CONTACT: Frank Krivda, Office of Compliance and Enforcement, Consumer Product Safety Commission, 4440 East West Highway, Bethesda, MD 20814 (Mailing address: Washington, D.C. 20207), telephone (301) 504–0400, ext. 1372.

SUPPLEMENTARY INFORMATION:

A. Background

In 1979, the Commission promulgated regulations to identify and ban products which contain small parts that present choking or aspiration hazards to children under three years of age (''the small parts regulation''). The regulation, in part, prescribes a test method to determine whether small parts are present in a product as marketed or after the product is subjected to reasonably foreseeable use or abuse. The regulation also exempts a number of products such as finger paints, modeling clay, writing materials, and children's grooming, feeding, and hygiene products from the testing requirements because they cannot be manufactured in a manner that passes the testing requirements and still remain functional.

In 1994, the Child Safety Protection Act (''CSPA'') established, *inter alia*, labeling requirements for toys and games that contain small parts and are intended for children between the ages of three and six. 15 U.S.C. 1278. The primary purpose of these requirements is to alert prospective purchasers that such products are not appropriate for children under three years of age because of the potential choking hazard. On February 27, 1995, the Commission published a regulation to implement the requirements of the CSPA. 60 FR 10742. The Commission considered the issue raised by commenters of whether toys or games exempt from the small parts regulation (''otherwise exempt products'') require labeling when they are intended for children between three and six years of age. The Commission discussed the issue in the preamble to the final rule, 60 FR 10749, but left it unresolved, pending appointment of a third Commissioner.

Neither the CSPA nor its legislative history expressly address whether otherwise exempt products require labeling when they are intended for children three to six years of age. However, requiring labeling for such products would create an apparent inconsistency with requirements of the small parts regulation. Specifically, if

the CSPA applied, an otherwise exempt product with a small part intended for children between three and six would require labeling alerting purchasers of the hazards of the product to children under three. However, if the same product were intended for children under three, it would neither be banned nor require any labeling, even though it presented the very same hazard. Of even greater difficulty, if an exempt product intended for children two to five years old (as often happens) required labeling under the CSPA because some of its users were over three, the product would theoretically have to bear a warning not to purchase the product for children under three, even though it is specifically intended for two to three year old children.

In view of the foregoing, the Commission is revising the final labeling rule under the CSPA to clarify that products containing small parts and intended for children at least three years of age but less than six years old, are exempt from the labeling requirements if the same products, when intended for children under three, would be exempt from the small parts banning regulation. This labeling exemption does not, however, apply to balloons, which the CSPA expressly requires to bear precautionary labeling. 15 U.S.C. 1278(b)(1).

B. Notice

The Commission issued a notice of proposed rulemaking (''NPR'') concerning the labeling requirements of the CSPA on July 1, 1994, 59 FR 33932, which provided an opportunity for comments on issues including labeling of exempt products. Comments on this issue were received, and these were discussed in the preamble to the final rule, but the Commission did not resolve the issue. See 60 FR 10742, 10749. Because the NPR provided an opportunity for public comment, no additional NPR is necessary.

C. Impact on Small Businesses

In accordance with section 3(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commission certifies that this regulation will not have a significant economic impact upon a substantial number of small entities if issued on a final basis. Inasmuch as the revision exempts certain products from the labeling requirements of the CSPA, it imposes no obligation on any entity. Therefore, the revision itself will not have a significant economic impact on small businesses, either beneficial or negative.

D. Environmental Considerations

This action falls within the provisions of 16 CFR 1021.5(c), which designates categories of actions conducted by the Consumer Product Safety Commission that normally have little or no potential for affecting the human environment. The Commission does not believe that the revision contains any unusual aspects which may produce effects on the human environment, nor can the Commission foresee any circumstance in which the rule issued below may produce such effects. For this reason, neither an environmental assessment nor an environmental impact statement is required.

E. Effective Date

This revision will become effective immediately upon publication of the final regulation in the **Federal Register**. The immediate effective date is appropriate because the revision brings no change in current practice. In the preamble to the February 27, 1995 rule, the Commission stated that until the Commission voted on this issue, ''toys and games that are exempted from the requirements of the small parts regulation by 16 CFR 1501.3 are not required to bear labeling under the act.'' 60 FR 10749. This rule continues the interpretation that exempt products do not require labeling under the CSPA. Thus, the Commission determines that there is good cause for an immediate effective date.

List of Subjects in 16 CFR Part 1500

Business and industry, Consumer protection, Hazardous materials, Infants and children, Labeling, Packaging and containers, toys.

Conclusion

Therefore, pursuant to the authority of the Child Safety Protection Act [Pub. L. No. 103–267), sections 10(a) and 24(c) of the Federal Hazardous Substances Act (15 U.S.C. 1269(a) and 1278(c)), and 5 U.S.C. 553, the CPSC amends Title 16 of the Code of Federal Regulations, Chapter II, Subchapter C, Part 1500 as set forth below:

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES; ADMINISTRATION AND ENFORCEMENT REGULATIONS

1. The authority for Part 1500 continues to read as follows:

Authority: 15 U.S.C. 1261–1278, 2079.

2. Section 1500.19(b)(1) introductory text preceding the warning statement is revised to read as follows:

§ 1500.19(b) Misbranded toys and other articles intended for children.

* * * * *

(1) With the exception of books and other articles made of paper, writing materials such as crayons, chalk, pencils, and pens, modeling clay and similar products, fingerpaints, watercolors, and other paint sets, and any other article identified in 16 CFR 1501.3 (other than balloons), any article that is a toy or game intended for use by children who are at least three years old but less than six years of age shall bear or contain the following cautionary statement if the toy or game includes a small part:

* * * * *

Dated: August 3, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 95–19627 Filed 8–11–95; 8:45 am]

BILLING CODE 6355–01–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 30

Foreign Option Transactions; Material Changes in Terms and Conditions of Option Contract

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission (Commission) is publishing notice of certain material changes in the terms and conditions of the option contract on the MIBOR '90 futures contract traded on the MEFF Sociedad Rectora de Productos Financieros Derivados de Renta Fija, S.A. (MEFF Renta Fija) to be offered or sold to persons located in the United States. The initial order permitting, among others, option contracts on the MIBOR '90 futures contract to be offered or sold to persons in the United States was issued on June 5, 1995, 60 FR 30462 (June 9, 1995), pursuant to Commission rule 30.3(a), 17 CFR 30.3(a), which makes it unlawful for any person to engage in the offer or sale of a foreign option product until the Commission, by order, authorizes such foreign option to be offered or sold in the United States.

EFFECTIVE DATE: August 14, 1995.

FOR FURTHER INFORMATION CONTACT: Jane C. Kang, Esq., or Robert Rosenfeld, Esq., Division of Trading and Markets, Commodity Futures Trading Commission, 2033 K Street, N.W.,

Washington, D.C. 20581. Telephone: (202) 254–8955.

SUPPLEMENTARY INFORMATION: The Commission has issued the following Notice:

Notice of Certain Material Changes in Terms and Conditions of the Option Contract on the MIBOR '90 Futures Contract Previously Approved Under Commission Rule 30.3(a) Permitting Option Contracts on MEFF Renta Fija to be Offered or Sold in the United States.

By Order issued on June 5, 1988 (Initial Order), the Commission authorized, pursuant to Commission rule 30.3(a),[1] certain option products traded on the MEFF Renta Fija to be offered or sold in the United States. 60 FR 30462 (June 9, 1995). Among other conditions, the Initial Order specified that:

Except as otherwise permitted under the Commodity Exchange Act and regulations thereunder, * * * no offer or sale of any MEFF Renta Fija option product in the United States shall be made until thirty days after publication in the **Federal Register** of notice specifying the particular option(s) to be offered or sold pursuant to this Order.

By letter dated July 6, 1995, MEFF Renta Fija through its counsel represented that it would be replacing the existing option contract on the MIBOR '90 futures contract with the option on the MIBOR '90 Plus futures contract, which has a notional value ten (10) times greater than the MIBOR '90 futures contract underlying the option previously approved by the Initial Order.[2] Counsel has confirmed that the options on the MIBOR '90 Plus futures contract commenced trading on June 12, 1995 and that the option on the MIBOR '90 futures contract has now been delisted.

MEFF Renta Fija has requested that the Commission confirm that its Initial Order authorizing options on the MIBOR '90 futures contract, the monthly option on the 10-year Government Bond futures contract and the Quarterly option on the 10-year Government bond futures contract, is amended to substitute options on the MIBOR '90 Plus futures contract for the previously approved MIBOR '90 option contract. Since the increase in the notional value of the futures contract underlying the previously authorized MIBOR '90 option is considered to be a material change in the existing option contract, the Commission is publishing the new terms and conditions of the option contract on the MIBOR '90 Plus futures contract for notice purposes only. The Commission also is amending Appendix B to Part 30 of its regulations to reflect this change.

Contract Specifications Options on the MIBOR '90 Plus Futures Contact

Underlying Asset

MIBOR '90 Plus futures contract. The underlying asset of the 90-day interbank deposit future is the interest paid on an interbank deposit, theoretically placed on the contract's maturity day, for a period of ninety days and an amount of one hundred million pesetas.

Contract Size

1 futures contract.

Exercise Style

American.

Traded Options

Options on futures with trading available at least in March, June, September and December in addition to the same quarters of the following year.

Available Classes

At least one options class for each of the underlying asset's two nearby expirations shall be available for trading.

Available Series

On the first trading day of an expiration at least five series of calls and five series of puts shall be introduced for the same underlying asset with the same expiration month, but with different strike prices.

For one of the call or put series, the strike price will be equal to the daily settlement price of the underlying asset the day prior to the option's first trading day, rounded off to the nearest strike price interval.

For the other series, the strike price shall be set so that there are at least two options series with strikes above and at least two series with strikes below the first strike price.

Trading Hours

8:00 a.m. to 10:00 p.m.

Last Trading Day

The last business day prior to the expiration date.

Expiration Date

Third Wednesday of the underlying futures contract month; if the expiration date coincides with a holiday, the expiration date shall be the following business day.

Quotation Method

Quoted in points, with one point equals two hundred and fifty pesetas.

Tick Value

The minimum fluctuation of the premium shall be 1 point.

Margining

Margin is calculated taking into account the overall futures and options portfolio.

List of Subjects in 17 CFR Part 30

Commodity futures, Commodity options, Foreign transactions.

Accordingly, 17 CFR Part 30 is amended as set forth below:

PART 30—FOREIGN FUTURES AND FOREIGN OPTION TRANSACTIONS

1. The authority citation for Part 30 continues to read as follows:

Authority: Secs. 2(a)(1)(A), 4, 4c, and 8a of the Commodity Exchange Act, 7 U.S.C. 2, 6, 6c and 12a.

2. Appendix B to Part 30 is amended by adding the following entry in alphabetical order to read as follows:

APPENDIX B—Option Contracts Permitted To Be Offered or Sold in the U.S. Pursuant to § 30.3(a)

Exchange	Type of contract	FR date and citation
* * *	* * *	*
MEFF Sociedad Rectora de Productos Financieros Derivados de Renta Fija, S.A.	Option Contracts on the MIBOR '90 Plus Futures Contract.	August 14, 1995; 60 FR 41803
* * *	* * *	*

[1] Commission rule 30.3(a), 17 CFR 30.3(a), makes it unlawful for any person to engage in the offer or sale of a foreign option product until the Commission, by order, authorizes such foreign option to be offered or sold in the United States.

[2] *See* letter dated July 6, 1995 from Philip McBride Johnson, Skadden, Arps, Slate, Meagher & Flom to Jean A. Webb, CFTC Secretary.

Issued in Washington, D.C. on August 8, 1995.

Jean A. Webb,

Secretary to the Commission.

[FR Doc. 95–19982 Filed 8–11–95; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 101 and 122

[T. D. 95–62]

Establishment of New Port-Rockford, Illinois

AGENCY: Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations pertaining to Customs field organization by establishing a new port of entry in the Customs District of Chicago, Illinois, North Central Region at Rockford, Illinois, and by deleting Greater Rockford Airport from the list of user fee airports. The new port of entry will include Greater Rockford Airport, which is currently operated as a user fee airport. This change will assist the Customs Service in its continuing efforts to achieve more efficient use of its personnel, facilities, and resources, and to provide better service to carriers, importers, and the general public.

EFFECTIVE DATE: September 13, 1995.

FOR FURTHER INFORMATION CONTACT: Mr. Brad Lund, Office of Field Operations, 202–927–0192.

SUPPLEMENTARY INFORMATION:

Background

In order to achieve more efficient use of its personnel, facilities, and resources, and in order to provide better service to carriers, importers, and the public in the North Central Region, Customs is amending its regulations to include Rockford, Illinois, as a port of entry. The new port of entry will include Greater Rockford Airport, which is currently, but will no longer be, a user fee airport. Section 101.3, Customs Regulations (19 CFR 101.3) is amended to add Rockford, Illinois to the list of Customs ports, and § 122.15, Customs Regulations (19 CFR 122.15) is amended by removing Greater Rockford Airport from the list of user fee airports.

In a Notice of Proposed Rulemaking published in the **Federal Register** on October 5, 1994 (59 FR 50717), Customs proposed these regulatory changes because it believes that there is sufficient justification for the establishment of a new port of entry at Rockford, Illinois.

Analysis of Comments

In its Notice of Proposed Rulemaking, Customs invited the public to comment on the proposed establishment of Rockford as a new port. One comment was received. The commenter stated that importer costs were reduced and that the time for Customs clearance and delivery of goods was reduced from 3 or 4 days to 1 day once Rockford became a user fee airport. He predicted that once Rockford becomes a full port of entry, the perceived permanency of the operation would encourage more companies to clear their imports at Rockford, thereby reducing the workload at other ports. He concluded that Rockford's new port status would benefit both Rockford and the Customs Service.

Conclusion

Inasmuch as the only comment received from the public was a positive one, the proposed amendments are adopted.

Description of Port Limits

The geographical limits of the new port of Rockford, Illinois, which include Greater Rockford Airport, are as follows:

Bounded to the north by the Illinois/Wisconsin border; bounded to the west by Illinois State Route 26; bounded to the south by Illinois State Route 72; and bounded to the east by Illinois State Route 23 north to the Wisconsin/Illinois border.

Regulatory Flexibility Act and Executive Order 12866

Customs routinely establishes, expands, and consolidates Customs ports of entry throughout the United States to accommodate the volume of Customs-related activity in various parts of the country. Thus, although a Notice of Proposed Rulemaking was issued with notice for public comment, because this matter relates to agency management and organization it is not subject to the notice and public procedure requirements of 5 U.S.C. 553. Accordingly, this document is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Because this document relates to agency organization and management, it is not subject to Executive Order 12866.

Drafting Information

The principal author of this document was Janet L. Johnson, Regulations Branch. However, personnel from other offices participated in its development.

Lists of Subjects

19 CFR Part 101

Customs duties and inspection, Exports, Imports, Organization and functions (Government agencies).

19 CFR Part 122

Air carriers, Aircraft, Airports, Customs duties and inspection, Freight.

Amendments to the Regulations

For the reasons set forth above, parts 101 and 122 of the Customs Regulations (19 CFR parts 101 and 122) are amended as set forth below.

PART 101—GENERAL PROVISIONS

1. The general authority citation for part 101 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 2, 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1623, 1624.

§ 101.3 [Amended]

2. Section 101.3(b) containing the list of Customs regions, districts and ports of entry is amended by adding ''Rockford, Ill. (T.D. 95–62)'' in the appropriate alphabetical order in the ''Ports of Entry'' column in the Chicago, Illinois district of the North Central Region.

PART 122—AIR COMMERCE REGULATIONS

1. The authority citation for part 122 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58b, 66, 1433, 1436, 1459, 1590, 1594, 1623, 1624, 1644; 49 U.S.C. App. 1509.

2. The list of user fee airports in § 122.15(b) is amended by removing the words ''Rockford, Ill.'' from the ''Location'' column and by removing the words ''Greater Rockford Airport'' on the same line from the adjacent ''Name'' column.

George J. Weise,

Commissioner of Customs.

Approved: July 31, 1995.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 95–19951 Filed 8–11–95; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 87C–0316]

Listing of Color Additives Exempt From Certification; Astaxanthin; Objection and Request for a Hearing; Staying Portions of the Regulation; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has received one objection to the final rule for astaxanthin as a color additive in the feed of salmonid fish to enhance the color of their flesh. The objection concerns a specification and the requirement for labeling of the color additive. The objection requests a hearing on the two issues. The submission of the objection stays the effective date of two paragraphs of the astaxanthin regulation until the agency can rule on them. FDA is confirming the effective date of May 16, 1995, for the remainder of this regulation that appeared in the **Federal Register** of April 13, 1995 (60 FR 18736).

DATES: Effective date confirmed: May 16, 1995, except for 21 CFR 73.35(b) for the specification for total carotenoids other than astaxanthin and 21 CFR 73.35(d)(3) for the labeling requirements.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3078.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 13, 1995 (60 FR 18736), FDA amended part 73 (21 CFR part 73) of its regulations to provide for the safe use of astaxanthin as a color additive in the feed of salmonid fish to enhance the color of their flesh.

FDA gave interested persons until May 15, 1995, to file objections and requests for a hearing on § 73.35 (21 CFR 73.35). The agency received from one color additive manufacturer objections to two provisions of the final rule. The objector requested a hearing on two issues: The specification for total carotenoids other than astaxanthin of not more than 4 percent under § 73.35(b) and the labeling requirement for the presence of the color additive in salmonid fish under § 73.35(d)(3). Under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)(2)) the objection stays the effect of these two paragraphs of the astaxanthin regulation until the agency has ruled on the objections. Apart from § 73.35(b) and (d)(3), FDA is confirming the effective date of May 16, 1995, for the final rule that amended the color additive regulations to provide for the use of astaxanthin as a color additive in the feed of salmonid fish to enhance the color of their flesh. The objections are on file in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, under the docket number found in the heading of this document.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 721 (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that because of the objection and request for a hearing on the specification for total carotenoids other than astaxanthin of not more than 4 percent in § 73.35(b) and the labeling requirement for the presence of the color additive in salmonid fish in § 73.35(d)(3), these provisions are stayed until further notice. Accordingly, the amendments to § 73.35 issued on April 13, 1995 (60 FR 18736), became effective May 16, 1995, except for §§ 73.35(b) and (d)(3), which are stayed until further notice.

Dated: August 7, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95–19946 Filed 8–11–95; 8:45 am]

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OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

29 CFR Part 2200

Rules of Procedure

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Final rule.

SUMMARY: The Occupational Safety and Health Review Commission has determined that it is in the public interest to adopt procedures that will permit the small employer who challenges an OSHA citation before the Commission to do so with minimal complexity and cost. Accordingly, it has decided to initiate a pilot E–Z Trial program for a one year period, beginning October 1, 1995. After the test period, the Commission will evaluate the results and determine whether it should continue the E–Z Trial program and, if so, what modifications should be made. The evaluation will involve surveying employers and employer representatives regarding their satisfaction with the fairness and efficiency of the process and analyzing data on the rate at which E–Z Trial cases go to a hearing, the length and cost of hearings and the cycle times of these cases as compared to those of conventional cases. We will also gather information from our Judges and the Solicitor of Labor and OSHA personnel regarding how well the process is working and how it might be changed or improved.

As the name implies, E–Z Trial is designed to simplify and accelerate adjudication for cases that warrant a less formal, less costly process. To ensure that the program is used sufficiently to enable the Commission to determine its success or failure, as well as its strengths and weaknesses, cases will be assigned to E–Z Trial by the Chief Administrative Law Judge. The Commission will also include explanatory materials on E–Z Trial in its Notice of Docketing to employers to make sure that (1) employers are well aware of the availability of the E–Z Trial option early in the process and (2) employers are clear on how they can apply for E–Z Trial. Together these mechanisms should encourage the use of E–Z Trial whenever appropriate. Parties who believe that an assigned case is inappropriate for E–Z Trial can present their reasons to the presiding Judge who, upon consultation with the Chief Judge, may order the case to proceed under conventional proceedings. In addition, a Judge assigned to a case could unilaterally direct that case to be tried under E–Z Trial proceedings. The Commission has also adopted certain rules and procedures designed to shorten the length of the proceedings. For example, the parties are required to disclose certain information to each other. Discovery, while not prohibited, is allowed only under the terms set by the presiding Judge, Interlocutory appeals are prohibited and, where practicable, the Judge is encouraged to render his or her decision from the bench. Any party dissatisfied with the disposition of the case may seek review of that decision as in conventional proceedings.

DATES: These revised rules will take effect on October 1, 1995. After September 30, 1996, § 2200.203(a) will no longer be in effect unless extended by the Commission by publication of a final rule in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Earl R. Ohman, Jr., General Counsel, One Lafayette Centre, 1120 20th St., N.W., 9th Floor, Washington, DC 20036–3419 Phone (202) 606–5410.

SUPPLEMENTARY INFORMATION:

Development of the Final Rules

On May 1, 1995, the Occupational Safety and Health Review Commission published in the **Federal Register** a proposal to revise its rules governing simplified proceedings and to institute a pilot E–Z Trial program (60 FR 21058). The notice explained the procedures followed by the Commission in developing its proposal and the basis and purpose of the proposed rules. The notice included a request for public comment.

In response, a number or organizations who would be affected by the revised rules filed comments with the E–Z Commission. The Office of the Solicitor of Labor, which represents the Secretary of Labor in all adjudicative proceedings before the Commission, filed comments on behalf of the Secretary of Labor. The following organizations, listed alphabetically, presented comments on the proposed revision to the rules: the Administrative Conference of the United States; the American Dental Association; Bell Atlantic Network Services, Inc.; General Building Contractors Association, Inc.; Gibson, Dunn & Crutcher; Jackson, Murdo, Grant & McFarland, P.C.; McDermott, Will & Emery; Morgan, Lewis & Bockius; the National Funeral Directors Association; the National Stone Association; Rader, Campbell, Fisher & Pyke; and Schottenstein, Zox & Dunn. The Commission gratefully acknowledges receipt of these comments and assures all commentators that their concerns about the proposed changes were fully considered, even though some are not specifically discussed here.

In developing the final rules set forth in this document, the Commission considered not only the concerns of the commentators, but also those of other interested parties. The Chairman and representatives of the Commission met with AFL–CIO affiliate unions on March 16, 1995, with members of the Solicitor's office on May 16, 1995, and on May 18, 1995, conducted two focus group sessions in Philadelphia, Pennsylvania, with attorneys, non-attorney representatives, and employers.

After careful consideration of all comments received, the Commission issues these E–Z Trial rules, amending its rules for simplified proceedings in order to promote more effective and efficient proceedings before the Commission's Judges while maintaining fairness to all its participants.

Eligibility for E–Z Trial

The Commission received several suggestions addressing § 2200.202, which sets forth which cases should be eligible for E–Z Trial. Several commentators noted that the importance and complexity of a case are often dependent on the required abatement, not the proposed penalty. One commentator suggested raising the $7500 penalty limitation, and including only those cases where the employer agrees that the cost of abatement would be $7500 or less. The Commission found this suggestion interesting because, as these commentators suggested, the higher the cost of abatement, the more complicated the issues in the case are likely to be. After considering the issue, however, the Commission has determined that the suggestion is not viable. While it is sometimes clear from the nature of the citation that the cost of abatement would be either substantial or relatively minor, the effect of the cost of abatement on the complexity of the case usually cannot be determined at the outset of the proceeding when the case file contains little more than the citation and notice of contest. Therefore, an instruction to the Chief Judge to exclude abatement over a certain dollar value would not be practicable. Similarly, it would be difficult to carry out one commentator's suggestion that only cases involving factual issues and not legal issues be directed for E–Z Trial. Certainly such cases would be most suitable for E–Z Trial. However, the Commission believes that such a separation of cases would be difficult, if not impossible, to perform, given the potential for legal issues arising in any case. We would expect that in most cases where the Chief Judge determines that the abatement called for in the citation would be expensive or the legal issues presented in the case are difficult, he would determine that the case is too complex to be a candidate for E–Z Trial.

The Commission has concluded that the $7500 limit originally proposed is too low. Upon examination of the Commission's case load, we are unable to discern a significant difference in complexity between cases with proposed penalties ranging from $7500 to $10,000. By considering cases for E–Z Trial with proposed penalties of not more than $10,000, the Chief Judge would have an expanded number of cases to choose from during this pilot project. Therefore, the Commission will instruct the Chief Judge to consider cases for E–Z Trial where the proposed penalties do not exceed $10,000 rather than $7500.

The Secretary suggested that the criteria used for Simplified Proceedings be adopted for E–Z Trial and that any case involving air contaminants (Subpart Z of Part 1910) be disqualified. The Secretary also suggested that cases which would appear to involve affirmative defenses should not be eligible for E–Z Trial because such cases usually require discovery and often become complicated. A commentator suggested that the specific requirements for E–Z Trial eligibility be set forth in the rule. The Commission agrees that the eligibility criteria be included in the rule. The Commission continues to believe, however, that during this pilot project, it should maintain the flexibility to apply broad eligibility criteria. Accordingly, the Commission expects that cases appropriate for E–Z Trial would generally include those with one or more of the following characteristics: (1) Relatively few citation items, (2) an aggregate proposed penalty of not more than $10,000, (3) no allegation of willfulness, (4) a hearing that is expected to take less than two days, or (5) a small employer whether appearing *pro se* or represented by counsel.

Procedures for Commencing and Discontinuing E–Z Trial

Many commentators objected to the language in § 2200.203(a) authorizing the Chief Judge to assign cases to E–Z Trial without either party's request or consent. Similarly, there was widespread belief that once selected for E–Z Trial, it would be very difficult to return the case to conventional proceedings. Generally, these commentators expressed concern over being forced into a proceeding that limited the availability of certain procedures, particularly discovery. One commentator even suggested that there be a ''presumption of correctness'' for employers wanting to opt out of E–Z Trial, and that the Judge be required to find ''overwhelming and compelling reasons why the case should be simplified.''

As we note, *infra*, the concern over the loss of discovery is overstated. Our paramount concern is always the conduct of a fair proceeding. The Commission does not intend to eliminate discovery. The rules

specifically grant authority to the presiding Judge to allow whatever discovery he finds appropriate.

Thus, where the Judge determines that extensive discovery is necessary, or finds some other reason for discontinuing E–Z Trial, § 2200.204(a) authorizes him to do so after consultation with the Chief Judge. The Commission does not foresee this consultation process as significantly restricting the presiding Judge from appropriately removing a case from E–Z Trial.

It is the Commission's view that making it too easy for the parties to opt out of E–Z Trial would run counter to the purpose of the program. Nonetheless, where a party believes that its case has been inappropriately assigned to E–Z Trial, § 2200.204(b) allows that party to move for the Judge to return the matter to conventional proceedings. The Commission expects that, upon a showing of good cause, most requests for returning a case to conventional proceedings will be granted. Joint motions to return a case to conventional proceedings shall be granted by the Judge and do not require a showing of good cause.

While the Commission recognizes the concern expressed by many commentators over the assignment of cases to E–Z Trial without the consent of the parties, it believes that such a mechanism is necessary. As the Commission stated in the preamble to the proposed E–Z Trial rules, the previous rules for Simplified Proceedings, which would take effect only upon a party's request, were rarely used. When Simplified Proceedings were requested by a party, the other party often filed and objection that was granted by the presiding judge. It is the Commission's goal that these E–Z Trial rules will increase the number of cases that use simplified proceedings to a significant level. The Commission hopes that after some experience with this process, litigants and their representatives will find it to be a useful alternative to our conventional trial process. Therefore, the Commission has set forth a sunset provision at § 2200.201(b). Under this provision, § 2200.203(a), which allows the Chief Judge to assign cases for E–Z Trial, will no longer be in effect after the conclusion of the plot program unless otherwise extended by the Commission.

Disclosure and Discovery

Most of the Commentators expressed reservations concerning the restrictions on discovery set for at § 2200.207. These commentators feared that the loss of discovery would severely curtail their ability to develop their case. A recurrent theme was that, without discovery, employers would be open to ''trial by ambush''and that the Secretary, by virtue of his inspection of the worksite, already had, in effect extensive discovery. Similarly, the Secretary of Labor was concerned that restrictions on discovery would prevent him from rebutting affirmative defenses raised by employers. Accordingly, the Secretary suggested that the rule be relaxed to allow discovery upon a showing of need.

We believe that these commentators have interpreted the intent of the rule. We are aware that E–Z Trial proceedings must be structured fairly. The proposed rule was designed to have the Judge take a more active role in the discovery process to ensure that it is limited to that which is necessary. By doing so, the Commission hoped to minimize delay and attendant costs. It appears that the role of discovery was too narrowly described in § 2200.200(b)(3) as being generally not permitted. We have modified this rule to more accurately reflect the intent of the Commission.

Because it is the intent of the Commission that E–Z Trial will enable the small employer to represent himself better, it is especially important that the Judge be involved in the discovery process. Few things could be more intimidating or confusing to a *pro se* employer than to receive a long list of interrogatories, requests for admission, or requests for production of documents or to have to partake in depositions. When such requests are made, the Commission expects that its Judges will restrict discovery that appears to be of marginal value.

It is the Commission's expectation that, as a result of reasonable restrictions on discover, the adjudicatory process will be substantially accelerated with significant cost savings being realized by both employers and the Secretary. The Commission expects that having the Judge take a more active role will expedite the case.

Several commentators observed that if discovery were to be restricted, the Secretary should be required to turn over his investigatory file to the employer early enough in the proceeding to enable the employer to evaluate the case against him and prepare a defense. We find this suggestion to be well-taken and have included a new § 2200.206 to require that the Secretary disclose to the employer certain information early in the proceeding. We note that it is already a general practice amongst some of the Commission's Judges to require the Secretary to turn over all or part of the investigatory file. In many other cases, the file is routinely turned over to the employer's counsel upon request. However, most *pro se* employers would not know that they have the right to request information contained in the investigative file. Therefore, by requiring that certain information in the file be turned over early in the proceeding, the employer would, in all cases, be given the basic documents necessary for the preparation of its defense.

The Secretary expressed the concern that requiring him to turn over the entire investigatory file in all cases would impose a substantial burden. Not only would the Secretary be required in every case to duplicate numerous documents, but he would also have to individually review each document to edit out any protected information. While we find these concerns to be well-founded, we note that mandatory pre-discovery disclosure is the trend in many jurisdictions, including the Federal Courts. For example, Federal Rule of Civil Procedure 26(a) requires the disclosure of certain basic information needed by parties to prepare for trial or make an informed decision about settlement.

For E–Z Trial, § 2200.206 sets forth the minimum disclosure requirements necessary for the parties to evaluate their case. The Commission has attempted to balance the employer's need for certain information necessary to its case against the burden it would impose on the Secretary to require the entire investigatory file to be turned over in every case. Therefore, the Commission has determined that it will require that two essential OSHA forms be turned over to the employer early in the proceeding: the compliance officer's narrative (Form OSHA–1A) and the worksheet (Form OSHA 1–B) or their equivalents. As part of his or her control over the discovery process, the presiding Judge would retain the authority to order that other materials be made available to the employer.

Simarily, the Commission believes that where an employer raises affirmative defenses, the Judge should require it to submit certain authenticating documents to the Secretary. For example, if an employer argues that a violation was the result of unpreventable employee misconduct, the Judge should, at a minimum, require it to submit to the Secretary a copy of the relevant portions of its safety manual and documentation establishing the scope and nature of employee discipline. The Commission has

codified this requirement at § 2200.206(b).

All rules after § 2200.206 have been renumbered to reflect the addition of the new rule § 2200.206, requiring the parties to disclose certain information.

Pre-Hearing Conference

Because the Commission will require the Secretary to provide certain information to the employer early in the proceeding, § 2200.207(a) has been modified to require that the pre-hearing conference be held only after the employer has had sufficient time to review the documents. Under § 2200.206(b), where affirmative defenses are raised, either before or at the pre-hearing conference, the Secretary will have the right, outside of discovery, to obtain certain authenticating documents from the employer. The Commission expects that, in the usual case, at the pre-hearing conference the Judge will be in the best position to determine what, if any, discovery should be allowed.

The Secretary of Labor suggested that a binding statement of all issues in dispute, including any affirmative defenses, be made part of a written conference order. The Secretary of Labor also requested that a rule be included requiring that a hearing date be set at the pre-hearing conference, and that the conference be held sufficiently in advance of the hearing date to allow the parties time to plan the presentation of the case.

It is the Commission's view that its Judges functions best when they have the flexibility to manage their cases in a manner that allows them to consider the requirements and idiosyncracies of the individual cases. However, the Secretary's suggestion that the rules specify that the pre-hearing conference be held sufficiently in advance of the hearing to allow the parties to prepare their case is well-taken. While we do not adopt a rule requiring when a hearing date be set, wherever practicable, the Judge should set a hearing date before the pre-hearing conference takes place. Accordingly, the Commission has modified § 2200.209(a) to clarify that the hearing be held ''as soon as practicable after the conclusion of the pre-hearing conference.'' Any agreements reached in the pre-hearing conference should be memorialized in a pre-hearing order.

Hearing

This proposed rule, now numbered § 2200.209, engendered comments in three areas.

Three commentators expressed reservations over § 2200.209(c), which makes the Federal Rules of Evidence inapplicable to E–Z Trial. These commentators suggested that elimination of the Federal Rules of Evidence would place the *pro se* employer at a disadvantage vis-a-vis the trained lawyers representing the Secretary; would result in the creation of a second, duplicative, system of evidentiary rules; and would allow the Secretary of Labor to introduce hearsay evidence that, when combined with the restrictions on discovery, the employer would be unable to refute.

The Commission adheres to its view that the efficacy of E–Z Trial will be enhanced, especially for the *pro se* employer, by not requiring the Judge to strictly adhere to the Federal Rules of Evidence. The Commission is confident that its Judges are fully able to deal with issues of the reliability and probative value of evidence. On the other hand, contrary to the contentions of the commentators, it seems obvious that *pro se* employers, with no legal training, would be at a substantial disadvantage in presenting their case if they were required to strictly adhere to the Federal Rules of Evidence.

Several commentators also objected to the prohibition on interlocutory appeals. One commentator noted that, because they are rarely used, the prohibition was probably unnecessary. Another commentator objected to the prohibition because the parties would have no immediate appeal should the Judge improperly force the case to continue under E–Z Trial. This latter comment underscores the reason why the Commission has concluded it is necessary to prohibit interlocutory appeals. Because of the unfamiliarity with these new procedures, we expect that some parties will try to opt out even when they are unable to show good cause why the case should not continue under E–Z Trial. To allow these parties to seek interlocutory review of the Judge's order, or to challenge other orders issued by the Judge, such as discovery orders, would gravely slow down the process and undermine the basic goal of E–Z Trial. We note that, despite the prohibition on interlocutory review, the parties retain the right, under § 2200.211, to petition the Commission to review the Judge's disposition.

Two commentators also specifically objected to § 2200.209(f) which encourages Judges to issue decisions from the bench. They contended that without a written opinion, the rationale for the Judge's decision would be incomplete, making it difficult both for other parties to rely on the decision and for review of the decision on appeal. Because we never intended to allow decisions without a recorded rationale, we have clarified the rule accordingly. All our Judges' decisions must comply with the Administrative Procedure Act. Therefore, the revised language explicitly requires the Judge to state his or her findings of fact and conclusions of law for the record. Moreover, the Judge will be required to reduce his or her order to writing and to include in his or her order all paragraphs from the transcript that contain findings of fact and conclusions of law that support the decision. This written order will serve as the official decision for purposes of appeal.

Commission Review

Several comments suggested a misunderstanding as to when a case would be considered for Commission review. In the preamble to these proposed rules, the Commission stated that the decision to place a case under E–Z Trial would only be reviewed when the losing party can show that they have been materially prejudiced either by the use of E–Z Trial rather than conventional proceedings or by a lack of due process during those proceedings, provided objections to use the E–Z Trial procedure were raised in a timely fashion to the Judge. This limitation is intended to apply strictly to those instances where a party seeks review of the *decision* to place the case under E–Z Trial and, in no way, is intended to limit the availability of Commission review for any other allegation of error.

Other Issues

1. Effect of E–Z Trial on Settlement

The Secretary expressed the serious concern that the availability of E–Z Trial may have the unintended consequence of reducing the percentage of cases that settle before hearing. The Secretary pointed out that requiring parties to examine the merits of their case when responding to pleadings, and the very requirement that responses be filed often serve as inducements to settlement. By eliminating pleadings, the Secretary suggests that it will become easier for employers to simply let their cases drift toward a hearing. According to the Secretary, many of the benefits sought by E–Z Trial could be achieved through the simple expedient of extending the deadline for the filing of the complaint. This, he argues, would allow the parties more time for settlement negotiations and the drafting, execution and submission of settlement documents.

The Commission shares the Secretary's concern. The Commission

always has sought to encourage the amicable settlement of its cases. In no way do we desire to undermine this goal. It is the Commission's hope that by directing the Judge to take an active role in narrowing and defining the issues at the pre-hearing conference, parties will be more likely, not less likely, to determine that settling their cases rather than going to a hearing is in their best interest. The Commission would also stress to *pro se* employers, and would expect its Judges to transmit this point during the pre-hearing conference, that E–Z Trial only cuts out some procedural red tape and does not imply that it will be easier for employers to prevail in their contests. Nonetheless, we are acutely aware that a reduction in settlements may be an unintended consequence of E–Z Trial. This is a major reason for the pilot nature of this project. We will be watching this issue closely for the duration of the pilot project.

2. Convert into Mini-Trial Pilot

The Secretary suggested that the Commission convert E–Z Trial into a mini-trial pilot where a party could request a *de novo* proceeding under conventional rules before the Judge. The Secretary opines that this would give the small employer an opportunity to state its case to the Judge while protecting the interests of the litigants when they believe that their case could only be adequately presented under conventional proceedings.

The Commission finds no merit in this proposal. It is the Commission's opinion that in most cases the Secretary's proposal would amount to little more than giving the parties a ''second bite of the apple,'' and would further strain the Commission's limited resources. In some cases, the parties can invoke the Commission's settlement Judge rule, § 2200.101, to accomplish the same result. The purpose of E–Z Trial is to streamline and shorten the adjudicatory process; not to lengthen the process by giving every losing party an opportunity to retry their case.

The Secretary also suggested that, given the streamlining of the adjudicatory process, Judges' decisions rendered after E–Z Trial should have no precedential value. However, unreviewed opinions of Judges do not presently constitute precedent binding on the Review Commission. An unreviewed Judge's decision issued after an E–Z Trial would likewise not be binding on the Commission. Conversely, a Commission decision would have precedential value whether it resulted from E–Z Trial proceedings or regular proceedings. Additionally, if on review the Commission is of the view that due process had not been adequately provided, the case could be remanded to the Judge.

3. Grandfather Clause

One commentator suggested exempting those who currently practice before the Commission from having their cases assigned to E–Z Trial. We find no purpose to be served by granting an exemption to anyone who has previously represented parties before the Commission. E–Z Trial is designed to benefit parties, not their representatives. It would countermand the purpose of E–Z Trial to force a party to have a conventional proceeding for no reason other than its choice of legal representative.

List of Subjects in 29 CFR Part 2200

Administrative practice and procedure, Hearing and appeal procedures.

For the reasons set forth in the preamble, the Occupational Safety and Health Review Commission amends Title 29, Chapter XX, Part 2200 of the Code of Federal Regulations as follows:

PART 2200—RULES OF PROCEDURE

1. The authority citation continues to read as follows:

Authority: 29 U.S.C. 661(g).

2. Subpart M is revised to read as follows:

Subpart M—E–Z Trial

Sec.

2200.200 Purpose.
2200.201 Application.
2200.202 Eligibility for E–Z Trial.
2200.203 Commencing E–Z Trial.
2200.204 Discontinuance of E–Z Trial.
2200.205 Filing of pleadings.
2200.206 Disclosure of Information.
2200.207 Pre-hearing conference.
2200.208 Discovery.
2200.209 Hearing.
2200.210 Review of Judge's decision.
2200.211 Applicability of Subparts A through G.

Subpart M—E–Z Trial

§ 2200.200 Purpose.

(a) The purpose of the E–Z Trial subpart is to provide simplified procedures for resolving contests under the Occupational Safety and Health Act of 1970, so that parties before the Commission may reduce the time and expense of litigation while being assured due process and a hearing that meets the requirements of the Administrative Procedure Act, 5 U.S.C. 554. These procedural rules will be applied to accomplish this purpose.

(b) Procedures under this subpart are simplified in a number of ways. The major differences between these procedures and those provided in subparts A through G of the Commission's rules of procedure are as follows.

(1) Complaints and answers are not required.

(2) Pleadings generally are not required. Early discussions among the parties and the Administrative Law Judge are required to narrow and define the disputes between the parties.

(3) The Secretary is required to provide the employer with certain informational documents early in the proceeding.

(4) Discovery is not permitted except as ordered by the Administrative Law Judge.

(5) Interlocutory appeals are not permitted.

(6) Hearings are less formal. The Federal Rules of Evidence do not apply. Instead of briefs, the parties will argue their case orally before the Judge at the conclusion of the hearing. In many instances, the Judge will render his or her decision from the bench.

§ 2200.201 Application.

(a) The rules in this subpart will govern proceedings before a Judge in a case chosen for E–Z Trial under § 2200.203.

(b) *Sunset Provision.* Section 2200.203(a), which permits the Chief Administrative Law Judge to assign a case for E–Z Trial, will no longer be effective after September 30, 1996 unless the rule is extended by the Commission by publication of a final rule in the Federal Register. After September 30, 1996, a case will only be assigned to E–Z Trial if the assignment is requested by a party.

§ 2200.202 Eligibility for E–Z Trial.

Those cases selected for E–Z Trial will be those that do not involve complex issues of law or fact. Cases appropriate for E–Z Trial would generally include those with one or more of the following characteristics:

(a) relatively few citation items,

(b) an aggregate proposed penalty of not more than $10,000,

(c) no allegation of willfulness,

(d) a hearing that is expected to take less than two days, or

(e) a small employer whether appearing *pro se* or represented by counsel.

§ 2200.203 Commencing E–Z Trial.

(a) *Selection.* Upon receipt of a Notice of Contest, the Chief Administrative Law Judge may, at his or her discretion, assign an appropriate case for E–Z Trial.

(b) *Party request.* Within twenty days of the notice of docketing, any party may request that the case be assigned for E–Z Trial. The request must be in writing. For example, ''I request an E–Z Trial'' will suffice. The request must be sent to the Executive Secretary. Copies must be sent to each of the other parties.

(c) *Judge's ruling on request.* The Chief Judge or the Judge assigned to the case may grant a party's request and assign a case for E–Z Trial at his or her discretion. Such request shall be acted upon within fifteen days of its receipt by the Judge.

(d) *Time for filing complaint or answer under § 2200.34.* If a party has requested E–Z Trial or the Judge has assigned the case for E–Z Trial, the times for filing a complaint or answer will not run. If a request for E–Z Trial is denied, the period for filing a complaint or answer will begin to run upon issuance of the notice denying E–Z Trial.

§ 2200.204 Discontinuance of E–Z Trial.

(a) *Procedure.* If it becomes apparent at any time that a case is not appropriate for E–Z Trial, the Judge assigned to the case may, upon motion by any party or upon the Judge's own motion, discontinue E–Z Trial and order the case to continue under conventional rules. Before discontinuing E–Z Trial, the Judge will consult with the Chief Judge.

(b) *Party Motion.* At any time during the proceedings any party may request that the E–Z Trial be discontinued and that the matter continue under conventional procedures. A motion to discontinue must be in writing and explain why the case is inappropriate for E–Z Trial. All other parties will have seven days from the filing of the motion to state their agreement or disagreement and their reasons. Joint motions to return a case to conventional proceedings shall be granted by the Judge and do not require a showing of good cause.

(c) *Ruling.* If E–Z Trial is discontinued, the Judge may issue such orders as are necessary for an orderly continuation under conventional rules.

§ 2200.205 Filing of pleadings.

(a) *Complaint and answer.* Once a case is designated for E–Z Trial, the complaint and answer requirements are suspended. If the Secretary has filed a complaint under § 2200.34(a), a response to a petition under § 2200.37(d)(5), or a response to an employee contest under § 2200.38(a), and if E–Z Trial has been ordered, no response to these documents will be required.

(b) *Motions.* A primary purpose of E–Z Trials is to eliminate, as much as possible, motions and similar documents. A motion will not be viewed favorably if the subject of the motion has not been first discussed among the parties.

§ 2200.206 Disclosure of Information.

(a) *Disclosure to employer.* Within 12 working days after a case is designated for E–Z Trial, the Secretary shall provide the employer, free of charge, copies of the narrative (Form OSHA 1–A) and the worksheet (Form OSHA 1–B), or the equivalent. The Judge shall act expeditiously on any claim by the employer that the Secretary improperly withheld or redacted any portion of the documents on the grounds of confidentiality or privilege.

(b) *Disclosure to the Secretary.* Where the employer raises an affirmative defense, the presiding Judge shall order the employer to disclose to the Secretary such documents relevant to the affirmative defense as the Judge deems appropriate.

§ 2200.207 Pre-hearing conference.

(a) *When held.* As early as practicable after the employer has received the documents set forth in § 2200.206(a), the presiding Judge will order and conduct a pre-hearing conference. At the discretion of the Judge, the pre-hearing conference may be held in person, or by telephone or electronic means.

(b) *Content.* At the pre-hearing conference, the parties will discuss the following: settlement of the case; the narrowing of issues; an agreed statement of issues and facts; defenses; witnesses and exhibits; motions; and any other pertinent matter. Except under extraordinary circumstances, any affirmative defenses not raised at the pre-hearing conference may not be raised later. At the conclusion of the conference, the Judge will issue an order setting forth any agreements reached by the parties and will specify in the order the issues to be addressed by the parties at the hearing.

§ 2200.208 Discovery.

Discovery, including requests for admissions, will only be allowed under the conditions and time limits set by the Judge.

§ 2200.209 Hearing.

(a) *Procedures.* As soon as practicable after the conclusion of the pre-hearing conference, the Judge will hold a hearing on any issue that remains in dispute. The hearing will be in accordance with Subpart E of these rules, except for §§ 2200.73 and 2200.74 which will not apply.

(b) *Agreements.* At the beginning of the hearing, the Judge will enter into the record all agreements reached by the parties as well as defenses raised during the pre-hearing conference. The parties and the Judge then will attempt to resolve or narrow the remaining issues. The Judge will enter into the record any further agreements reached by the parties.

(c) *Evidence.* The Judge will receive oral, physical, or documentary evidence that is not irrelevant, unduly repetitious or unreliable. Testimony will be given under oath or affirmation. The Federal Rules of Evidence do not apply.

(d) *Reporter.* A reporter will be present at the hearing. An official verbatim transcript of the hearing will be prepared and filed with the Judge. Parties may purchase copies of the transcript from the reporter.

(e) *Oral and written argument.* Each party may present oral argument at the close of the hearing. Post-hearing briefs will not be allowed except by order of the Judge.

(f) *Judge's decision.* Where practicable, the Judge will render his or her decision from the bench. In rendering his or her decision from the bench, the Judge shall state the issues in the case and make clear both his or her findings of fact and conclusions of law on the record. The Judge shall reduce his or her order in the matter to writing and transmit it to the parties as soon as practicable, but no later than 45 days after the hearing. All relevant transcript paragraphs and pages shall be excerpted and included in the decision. Alternatively, within 45 days of the hearing, the Judge will issue a written decision. The decision will be in accordance with § 2200.90. If additional time is needed, approval of the Chief is required.

(g) *Filing of Judge's decision with the Executive Secretary.* When the Judge issues a written decision, it shall be filed simultaneously with the Commission and the parties. Once the Judge's order is transmitted to the Executive Secretary, § 2200.90(b) applies, with the exception of the 21 day period provided for in rule § 2200.90(b)(2).

§ 2200.210 Review of Judge's decision.

Any party may petition for Commission review of the Judge's decision as provided in § 2200.91. After the issuance of the Judge's written decision or order, the parties may pursue the case following the rules in Subpart F.

§ 2200.211 Applicability of Subparts A through G.

The provisions of Subpart D (except for § 2200.57) and §§ 2200.34, 2200.37(d)(5), 2200.38, 2200.71, 2200.73 and 2200.74 will not apply to E–Z Trials. All other rules contained in Subparts A through G of the Commission's rules of procedure will apply when consistent with the rules in this subpart governing E–Z Trials.

Dated: August 8, 1995.

Earl R. Ohman, Jr.,

General Counsel.

[FR Doc. 95–19975 Filed 8–11–95; 8:45 am]

BILLING CODE 7600–01–M

DEPARTMENT OF COMMERCE

Assistant Secretary for Technology Policy

37 CFR Part 401

[Docket No. 950615153–5153–01]

RIN 0692–AA14

Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements; Electronic Filing of Written Submissions; Definition of the Term ''Patent Application'' or ''Application for Patent''

AGENCY: Assistant Secretary for Technology Policy, Commerce.

ACTION: Interim rule with request for comments.

SUMMARY: This interim rule (1) authorizes certain government contractors and grantees to report electronically to the funding agencies their inventions and respective election of title on agency-approved systems; (2) recognizes that the law now authorizes the filing of provisional U.S. patent applications by defining the term ''patent application'' or ''application for patent'' to include provisional patent applications; and (3) updates the name and address of the office to where all submissions and inquiries should be sent.

Federal agencies each year enter into many research funding agreements with nonprofit organizations and small business firms, which require them to submit written reports and other information to the agencies relating to inventions made under the funding agreements. The reports and information must then be manually processed by the agencies. A number of these contractors, grantees and agencies have established computer systems for keeping track of their inventions. It is desirable to utilize these systems to facilitate the invention reporting requirements by permitting contractors and grantees to submit reports and information to the agencies in electronic form. This would result in a reduction of time, paper and postage for the contractors and grantees and allow the agencies to more easily keep track of the inventions.

DATES: Interim rule effective August 14, 1995; comments must be received on or before September 13, 1995.

ADDRESSES: Comments may be mailed to Mr. Jon Paugh, Director, Technology Competitiveness Staff, Office of Technology Policy, Room 4418, Herbert C. Hoover Building, U.S. Department of Commerce, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Mr. Jon Paugh at telephone: (202) 482–2100.

SUPPLEMENTARY INFORMATION: Under the authority of 35 U.S.C. 206 and the delegation by the Secretary of Commerce in sec. 3(g) of DOO 10–18, the Assistant Secretary of Commerce for Technology Policy may issue revisions to 37 CFR Part 401.

Under the rule now in effect, contractors and grantees must report in writing to the funding agencies their inventions and respective election of title. They may also be required to indicate if an invention was not made. The reports are then manually placed by the agencies in their respective contract or grant files, a very burdensome and time consuming task.

Therefore, in order to facilitate reporting by contractors and grantees, new §§ 401.16 (a) and (b) are being added to 37 CFR Part 401 to authorize certain government contractors and grantees to report electronically to the funding agencies their inventions and respective election of title on agency-approved electronic or optical-electronic systems. These changes will help the agencies to maintain an up-to-date record of government-funded inventions which can be used to automatically track the status of these inventions so that rights in valuable inventions are not inadvertently lost.

New § 401.16(c) is being added to authorize a government contractor and grantee to electronically submit the close-out report in § 401.5(f)(1) and the information identified in §§ 401.5(f) (2) and (3), which at the present time, although not required, are usually submitted in writing to the agencies.

This rule change does not require contractors and grantees to electronically report their inventions to the Federal agencies and some may wish to continue to communicate in writing. However, since a number of contractors and grantees have established computer systems to track their own inventions, it is expected that they would be interested in reporting their inventions electronically to the agencies. For this purpose, an electronic system named ''EDISON'' is being developed by the Division of Extramural Invention Reporting of the National Institutes of Health which will allow various contractors and grantees to submit certain information on their inventions by computer to the agencies. For information on EDISON, Sue Ohata, Acting Director, Division of Extramural Invention Reporting, NIH may be contacted at (301) 402–0850, by fax (301) 480–8443 or by e-mail at ohata@NIHOD1.bitnet.

New paragraphs (k) and (l) are being added to § 401.2 in order to define the terms ''electronically filed'' and ''electronic or optical-electronic system'' which are used in the new § 401.16.

Section 401.2(j) is being amended to define the term ''Secretary'' as the Assistant Secretary of Commerce for Technology Policy to conform with the authority citation for 37 CFR Part 401.

Public Law 103–465 amended 35 U.S.C. 111 to provide for the filing of provisional applications on or after June 8, 1995. To reflect this change in the law, the Patent and Trademark Office (PTO) amended 37 CFR Parts 1 and 3 to cover these provisional applications as indicated in the **Federal Register**, 60 FR 20195, April 25, 1995. The changes to 35 U.S.C. 111 and 37 CFR Parts 1 and 3 also affected 37 CFR Part 401. Accordingly, new paragraph (m) is being added to § 401.2 to recognize these changes by defining the term ''patent application'' or ''application for patent'' to include a provisional or nonprovisional U.S. national application for patent as defined in 37 CFR 1.9 (a)(2) and (a)(3), respectively, or an application for patent in a foreign country or in an international patent office.

New paragraph (n) is being added to § 401.2 to define the term ''initial patent application'' as a nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3) to make it clear that the requirements stated in paragraph (c) of the standard clause at § 401.14(a) and in paragraph (c) of § 401.13 are not being changed. These paragraphs are based on 35 U.S.C. §§ 202(c) and 205, respectively, which refer to a U.S. national patent application filed under 35 U.S.C. 111 before it was amended by the Uruguay Round Agreements Act (Public Law 103–465).

Section 401.5(f)(2) is being amended to refer to patent application number rather than serial number by replacing the term ''serial'' with ''patent application'' in order to conform to the change made by the PTO to the title and paragraph (a) of 37 CFR 1.53 as indicated in the **Federal Register**, 60 FR 20195, April 25, 1995.

Section 401.13(c)(2) has been editorially amended to refer to a patent application rather than just an application.

Finally, current § 401.16 is being redesignated as § 401.17 and the address to where any submissions or inquiries should be sent is being updated since the Federal Technology Management Policy Division is now the Technology Competitiveness Staff which is part of the Office of Technology Policy (OTP)/ Technology Administration.

Pursuant to section 553 of the Administrative Procedure Act (5 U.S.C. 553) (APA), the Assistant Secretary of Commerce for Technology Policy finds that there is good cause for waiving, as impracticable, unnecessary, and contrary to public interest, the prior notice of proposed rulemaking and the required 30-day delay in the effective date because: (1) This interim rule provides a contractor or grantee the opportunity to report electronically inventions and respective election of title to the funding agency using an agency-approved electronic system which may result in cost savings to the contractor, grantee and/or the funding agency; (2) These changes are not considered substantive; and (3) This interim rule provides a 30-day comment period and any comments received will be considered prior to finalization of this interim rule.

This interim rule has been determined to be significant for purposes of E.O. 12866 (58 FR 51735, October 4, 1993).

This interim rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under E.O. 12612.

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the APA (5 U.S.C. 553) or by any other law, under sections 3(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

This interim rule involves a collection of information which has approval under the Paperwork Reduction Act. The control number is 9000–0095.

List of Subjects in 37 CFR Part 401

Inventions, Patents, Nonprofit organizations, Small business firms.

For the reasons set forth in the preamble, 37 CFR part 401 is amended as follows:

PART 401—RIGHTS TO INVENTIONS MADE BY NONPROFIT ORGANIZATIONS AND SMALL BUSINESS FIRMS UNDER GOVERNMENT GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS

1. The authority citation for 37 CFR part 401 continues to read as follows:

Authority: 35 U.S.C. 206 and the delegation of authority by the Secretary of Commerce to the Assistant Secretary of Commerce for Technology Policy at sec. 3(g) of DOO 10–18.

2. Section 401.2 is amended by revising paragraph (j) to read as follows:

§ 401.2 Definitions.

* * * * *

(j) The term ''Secretary'' means the Assistant Secretary of Commerce for Technology Policy.

3. New paragraphs (k), (l), (m) and (n) are added to § 401.2 to read as follows:

§ 401.2 Definitions.

* * * * *

(k) The term *electronically filed* means any submission of information transmitted by an electronic or optical-electronic system.

(l) The term *electronic or optical-electronic system* means a software-based system approved by the agency for the transmission of information.

(m) The term *patent application* or ''application for patent'' includes a provisional or nonprovisional U.S. national application for patent as defined in 37 CFR 1.9 (a)(2) and (a)(3), respectively, or an application for patent in a foreign country or in an international patent office.

(n) The term *initial patent application* means a nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3).

4. Section 401.5 is amended by revising paragraph (f)(2) to read as follows:

§ 401.5 Modification and tailoring of clauses.

* * * * *

(f) * * *

(2) Provide, upon request, the filing date, patent application number and title; a copy of the patent application; and patent number and issue date for any subject invention in any country in which the contractor has applied for a patent.

* * * * *

5. Section 401.13 is amended by revising paragraph (c)(2) to read as follows:

§ 401.13 Administration of patent rights clauses.

* * * * *

(c) * * *

(2) In accordance with 35 U.S.C. 205, agencies shall not disclose or release for a period of 18 months from the filing date of the patent application to third parties pursuant to requests under the Freedom of Information Act, or otherwise, copies of any document which the agency obtained under this clause which is part of an application for patent with the U.S. Patent and Trademark Office or any foreign patent office filed by the contractor (or its assignees, licensees, or employees) on a subject invention to which the contractor has elected to retain title. This prohibition does not extend to disclosure to other government agencies or contractors of government agencies under an obligation to maintain such information in confidence.

* * * * *

6. Section § 401.16 is redesignated as § 401.17 and revised to read as follows:

§ 401.17 Submissions and inquiries.

All submissions or inquiries should be directed to Director, Technology Competitiveness Staff, Office of Technology Policy, Technology Administration, telephone number 202–482–2100, Room H4418, U.S. Department of Commerce, Washington, D.C. 20230.

7. A new § 401.16 is added to read as follows:

§ 401.16 Electronic filing.

Unless otherwise requested or directed by the agency,

(a) the written report required in (c)(1) of the standard clause in § 401.14(a) may be electronically filed;

(b) the written election required in (c)(2) of the standard clause in § 401.14(a) may be electronically filed; and

(c) the close-out report in (f)(1) and the information identified in (f)(2) and (f)(3) of § 401.5 may be electronically filed.

Dated: August 7, 1995.

Graham Mitchell,

Assistant Secretary of Commerce for Technology Policy.

[FR Doc. 95–20023 Filed 8–11–95; 8:45 am]

BILLING CODE 3510–18–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 195

[FRL–5276–3]

RIN 2060–AF40

User Fees for Radon Proficiency Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Technical amendment.

SUMMARY: This technical amendment to the Radon Proficiency Program's User Fee establishes fees for the calendar year 1995. The User Fee Rule requires that individuals and organizations applying to or participating in the National Radon Measurement Proficiency (RMP) or the National Radon Contractor Proficiency (RCP) Programs pay annual fees. This amendment establishes the fee schedule for the calendar year 1995.

In 1994 the Agency began an aggressive effort to streamline operation of the proficiency programs as a way of reducing costs. Because of these streamlining efforts, the cost to operate the proficiency programs in 1994 was reduced by about 34% from 1993. Thus, the 1995 user fees will generally be lower than the 1994 user fees in some areas while the fees for other areas of the program will go up slightly from the 1994 user fees. The Agency remains committed to recovering all of its operating costs over a period of five years. Consistent with the schedule established in the 1994 User Fee Rule, the Agency has increased the level of anticipated cost recovery from 30% in 1994 to 47.5% in 1995.

Upon receipt of an invoice from EPA following the effective date of this technical amendment, organizations offering primary measurement services must pay an annual fee of $390 per device entered or listed in the RMP program. Organizations offering secondary measurement services must pay an annual fee of $50 for each business location listed in the program. Participants in the individual proficiency component of the RMP program must pay an annual fee of $105. Participants in the RCP program must pay an annual fee of $210. As before, State and local governments are exempted from these fees under section 305(e)(2) of the Indoor Radon Abatement Act of 1988, 15 U.S.C. 2665(e)(2).

EFFECTIVE DATE: September 13, 1995.

FOR FURTHER INFORMATION CONTACT: James W. Long, (202) 233–9433, U.S. EPA, Office of Radiation and Indoor Air, 401 M St. S.W., (6604J), Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

I. Authority

Section 305 of the Indoor Radon Abatement Act (IRAA) of 1988, 15 U.S.C. 2661 et seq., authorizes the Administrator of EPA to assess fees to defray the costs associated with operating its radon proficiency programs. The User Fees for Radon Proficiency Programs Final Rule, **Federal Register**, 59 FR 13166, established fees for two proficiency programs: the National Radon Measurement Proficiency Program and the National Radon Contractor Proficiency Program. The funds received by EPA have been authorized to be deposited into a special account in the United States Treasury with amounts in the account to be appropriated for administering the radon proficiency programs. State and local governments, including educational entities, are exempt from paying a fee to participate in the radon proficiency programs.

The final rule is cross-referenced to Title 40 of the Code of Federal Regulations (CFR) chapter I, subchapter R, Part 700 that lists regulations promulgated under the Toxic Substances Control Act (TSCA). Although the IRAA was enacted as Title III of TSCA, the Final User Fee Rule itself is listed under subchapter F of the CFR (40 CFR 195.20 et seq.) because it deals solely with a radiation program.

II. Background

On March 18, 1994, EPA issued a final rule in the **Federal Register**, 59 FR 13166, that established an initial fee schedule of $375 per device entered or listed in the RMP program for organizations offering primary measurement services, $75 per business location for organizations offering secondary measurement services, $150 for participants in the individual proficiency component of the RMP program, and $200 for participants in the RCP program.

The fees that the Agency established in the 1994 final rule were set to recover 30% of the total costs of administering the proficiency programs. As stated in the 1994 rule, the Agency intends to adjust its fees annually to recover ever increasing percentages of its program costs according to the following schedule: 1994 (30%), 1995 (47.5%), 1996 (65%), 1997 (82.5%) and 1998 (100%). For Fiscal Year (FY) 1994, total Agency costs to operate the radon proficiency programs were $1.7 million. EPA expects similar costs for fiscal year 1995. Based on a projected cost recovery percentage of 47.5%, the Agency expects to collect approximately $750,000 from user fees during 1995. EPA shall continue to review and adjust the fees over the next three years (as necessary) to recover ultimately the full annual costs of the proficiency programs. Fees may also be adjusted to account for other factors such as inflation and changes in programs costs. As it adjusts fees in the future, EPA will assess the potential effects of its fee adjustments on the radon industry and the regional impacts.

The Agency has determined that the Paperwork Reduction Act of 1980 (PRA) requirements do not apply to this technical amendment. This action was not classified by the Agency as a significant regulatory action, however, the Office of Management and Budget did request to review this action. The technical amendment cleared review on May 4, 1995 with no comments from OMB.

III. Provisions of the Amendment

A. National Radon Measurement Proficiency Program

EPA's total costs for the organizational component of the RMP Program for Fiscal Year 1994 were about $960,000 (a more detailed description of costs and how they were calculated is presented in the Technical Support Document for the 1995 User Fee Calculation in Support of the Radon Proficiency Program User Fee Final Rule, U.S. EPA/Office of Radiation and Indoor Air, January 24, 1995.). As of October 1, 1994, EPA had approximately 985 primary devices and approximately 1,485 secondary organizations listed or seeking to be listed in the program. If the RMP Program fees had been set at a full cost recovery level (100%) the annual fee for 1995 for a primary device would be about $825 per application or listing, and a fee of $100 would be assessed for each secondary firm applying to or listed in the RMP program. The difference between the fees for primary devices and secondary firms reflects differences in EPA's costs to process and maintain each type of applicant or participant in the organizational component of the RMP Program.

In this technical amendment to the 1994 Final Rule we have clarified the text in Section 195.20(a)(2) to reflect the fact that organizations listed or seeking to be listed for secondary measurement services in the RMP Program must pay an annual fee of $50 for each business location. Since the inception of the RMP

Program in 1989, EPA has required secondary organizations to submit applications and be listed separately for each business location they operate. In the 1994 user fee billing cycle, EPA invoiced and collected fees for organizations listed for or seeking listing for secondary measurement services based on separate business locations. To clarify this aspect of the program's operation, EPA has added the phrase, ''a fee for each business location listed'' at appropriate places in Section 195.20(a)(2) of the final rule.

B. Individual Measurement Proficiency

The total costs of the individual proficiency component of the RMP program in Fiscal Year 1994 were about $459,400. As of October 1, 1994, approximately 2,075 individuals were listed or in the process of being listed in the individual proficiency program. If the individual component of the RMP Program fees had been set at a full cost recovery level (100%) the annual fee for 1995 would be about $220 per individual.

C. National Radon Contractor Proficiency Program

The total costs for the RCP program were about $305,400 in fiscal year 1994. Approximately 686 individuals were listed or in the process of being listed in the RCP Program as of October 1, 1994. If the RCP Program fee had been set at a full cost recovery level (100%) the annual fee for 1995 would be about $445 per individual.

D. Fee Schedule—1995

1. Fee Amounts

The 1995 user fee schedule for applicants to and participants in the RMP and RCP programs is, apart from some minor editorial changes, essentially unchanged from 1994. That schedule appears as a revised 40 CFR section 195.20, which follows this preamble.

Organizations or individuals whose proficiency program application has not yet been accepted by EPA on the effective date of this technical amendment (i.e., 30 days after the date of its publication in the **Federal Register**) become subject to the fees described above once their application has been accepted. Their user fees will be prorated quarterly, based on the acceptance date of the application. New applicants will be assessed an annual user fee based on the acceptance date of their application.

2. Exemptions

State and local governments, including educational entities, are exempted from these fees under section 305(e)(2) of the IRAA. EPA has determined that exempted organizations or individuals include:

State or local governments (or employees thereof acting in their official capacities) who are listed, or applying to be listed, in the EPA proficiency programs who wish to perform radon measurements and/or mitigations. Specific exempted entities include the following classifications:

—Indian Tribes,
—State and local educational entities, that is, schools and school districts (this includes public universities, colleges and educational agencies), and
—State and local medical institutions and hospitals.

EPA has determined that IRAA does not exempt Federal employees from paying a fee to participate in the EPA proficiency programs.

3. Determination of Fees

Participants listed in the RMP and RCP programs on the effective date of this technical amendment will be sent, by EPA, a payment invoice with its fee calculation at least 30 days before the payment is due. Fees will be assessed based on the current information in EPA's proficiency data bases.

Participants who intend to pay the invoiced fee amount must send their payment to EPA following the procedures stated in the invoice. Organizations or individuals who wish to notify EPA of any errors or corrections they wish to make to their listing status must do so by following the instructions on the payment invoice. Corrected payment invoices for both the RMP Program and the RCP Program shall be sent to: Radon Proficiency Programs User Fees, c/o Sanford Cohen and Associates, Inc. (SC&A), 1418 I–85 Parkway, Montgomery, Alabama, 36106. EPA will review any corrections noted on the payment invoice, adjust the payment invoice amount (as appropriate) and issue a new invoice. Participants must pay the amount in the corrected payment invoice within 30 days of the date listed on the corrected invoice.

If the appropriate fee or a revised payment invoice for an individual or organization participating in the RMP or RCP program has not been received by EPA on or before the payment due date, EPA will send, by certified mail, notice that the individual or organization will be delisted from the proficiency program unless he/she pays the fee within 30 days of this second certified notification. If payment still has not been received by EPA on or before 30 days or after of the second certified notification, the organization's or individual's listing will be removed from the proficiency program.

New or initial applicants to the RMP or RCP programs will be assessed a fee at the time of their initial application. EPA will send a payment invoice to the new applicant upon acceptance of the initial application. The applicant will be given at least 30 days from the date on the payment invoice to remit payment. The fee assessed will be prorated quarterly, based on the acceptance date of the application. The prorated fee schedule for 1995 is as follows:

Quarter	1st Jan 1–Mar 31	2nd Apr 1–Jun 30	3rd Jul 1–Sep 30	4th Oct 1–Dec 31
RMP Program:				
Per Primary measurement device	1$390	$295	$195	$95
Per Organization listed for secondary services	50	40	25	10
Per Individual listed for measurement services	105	80	55	25
RCP Program;				
Per Individual listed for mitigation services	210	160	105	50

If the appropriate fee has not been received by EPA on or before the payment due date, the application will be placed in an inactive file with no further action taken by EPA.

4. Payment Procedures

Each remittance to EPA under this technical amendment must be in United States currency and must be paid by either certified check, personal or business check, or money order made payable to the order of the ''U.S. ENVIRONMENTAL PROTECTION AGENCY'' and sent to: U.S. EPA, Washington Financial Management

Center, Radon Proficiency Program User Fees (IRAA), P.O. Box 952491, St. Louis, Missouri, 63195–2491. The fee payment must include the original copy of the EPA payment invoice. Collection of fees will begin in the calendar year beginning January 1, 1995. Specific guidance on how and when fees must be paid can be found in How to Pay Your Radon Proficiency Programs User Fees, U.S. EPA/Office of Radiation and Indoor Air. Copies of this document can be obtained by contacting the RIS at (334) 272–2797 or by FAX at (334) 260–9051.

5. Failing the RMP Measurement Test

Organizations that fail the initial measurement device performance test or the re-test for a particular device must re-apply to the RMP program if they want to be listed or remain listed for that device. When the organization re-applies, EPA will send a payment invoice for the device(s) to be tested/re-tested. The appropriate user fee must be paid prior the scheduling of the test/re-test. EPA will send written notification of the measurement performance test results and listing status. Any fee paid to EPA in the process of attaining a listing of a particular device will not be refunded if the device fails to meet the RMP program criteria as stated in the Radon Measurement Proficiency (RMP) Program Handbook, EPA 402–B–94–003. Should the organization elect to re-apply to test the failed device, EPA will assess a new fee based on the information provided in the organization's application.

6. Failing the RMP Individual Proficiency and RCP Exams

a. *Biennial Reexamination.* To maintain their listing in the RCP program and/or the individual proficiency component of the RMP program, individuals must take and pass a biennial re-examination. EPA will notify listed participants of this requirement within 120 days of their exam expiration date. If an individual fails the exam, he/she may take the examination as often as he/she wishes during the same calendar year and not have to pay additional processing fees. This is a change from the 1994 final rule. In the final rule each application for retest also required that a $50.00 processing fee be paid. EPA has determined that it was not cost effective to assess and administer the $50.00 processing fee for retests.

Fees will not be refunded in the event that a participant fails the re-exam and/or chooses not to re-take the exam. If the same individual wishes to re-enter the program by re-taking the exam, the individual must re-apply. At the time that the application is submitted, EPA will determine whether a user fee will be assessed. Since user fees are paid for an entire year, so long as the original user fee was paid, an individual wishing to re-enter the proficiency programs within the same calendar year that he/she was delisted or failed the exam requirement, will not be assessed an additional user fee.

b. *New Applicants and the Exams.* New applicants to the RCP Program and/or the individual component of the RMP Program will be assessed a user fee when their application has been accepted. A user fee must be paid whether the individual passes or fails the exam. If an applicant decides not to re-take a failed individual RMP program proficiency exam or RCP exam, no further action is taken by EPA on the individual's application. Fees will not be refunded in the event that an applicant fails the exam and/or chooses not to re-take the exam. If the same individual wishes to re-apply to the program by re-taking the exam, at the time that the application is received, EPA will determine whether a user fee will be assessed. Since user fees are paid for an entire year, so long as the original user fee was paid, an individual wishing to re-enter the proficiency programs by meeting the examination requirement, will not be assessed an additional user fee.

7. *Adjustment of Fees*

EPA shall adjust the fees over the next three years to a level that will ultimately be sufficient to recover the full annual costs of the radon proficiency programs. Assuming that the Agency's cost of running the proficiency programs remains the same over the next three years and assuming that the level of participation in the proficiency programs remains constant, the fee schedule for the next three years would be as follows:

Program element	Fee year 3	Fee year 4	Fee year 5
RMP Program:			
Per Primary measurement device	$540	$680	$825
Per Organization listed for secondary services	65	80	100
Per Individual listed for measurement services	145	185	220
RCP Program:			
Per Individual listed for mitigation services	290	365	445

The above table should only be considered as a guide. Actual fees for each fiscal year will be adjusted based on program costs and participation rates. EPA may also use the three-step process outlined in the 1994 final rule to adjust the fees for years after 1995. If future fee adjustments are made, the Agency will publish new fee schedules in the **Federal Register** as a technical amendment final rule to become effective 30 days or more after publication, as specified in the 1994 final rule.

VI. Rulemaking Record

EPA has established a public record for this rulemaking (docket control number A–90–09). The record for this rulemaking is available to the public in the Clean Air Act Docket, located on the first floor Waterside Mall, room M1500, U.S. Environmental Protection Agency, 401 M St., SW, Mail Stop 6102, Washington, DC, 20460, open from 8:30 a.m. to 12 p.m. and 1:30 p.m. to 3:30 p.m., Monday through Friday, excluding legal holidays, (202) 260–7548.

The record includes information considered by EPA in developing this technical amendment. The record contains the following categories of information: (1) **Federal Register** notices: ''Fees for Radon Proficiency Programs and Training,'' Proposed Rule, FR vol. 55, No. 235, Thursday, December 6, 1990; ''User Fees for Radon Proficiency Program,'' Final Rule, FR vol. 59, No. 53, Friday, March 18, 1994; (2) Support Documents: ''Economic Impact Analysis of Radon Proficiency Program User Fee Rule—Final Report.'' U.S. EPA/Office of Radiation and Indoor Air, November 17, 1993; ''Technical Support Document for the 1995 User Fee Calculation in Support of the Radon Proficiency Programs User Fee Final Rule,'' U.S. EPA/Office of Radiation and Indoor Air, January 24, 1995; and, ''Operating Policies and Procedures for the User Fees for Radon Proficiency Programs Final Rule—Fee Collection Process,'' U.S. EPA/Office of Radiation and Indoor Air, June 19, 1995; (3) Public

Comments received during the proposed rule notice and comment period and those received by the Agency following publication of the 1994 final rule.

List of Subjects

40 CFR Part 195

Environmental protection, Radon, Proficiency programs, User fees.

40 CFR Part 700

Environmental protection, Radon, Proficiency programs, User fees.

Dated: August 7, 1995.

Carol M. Browner,

Administrator.

Therefore, 40 CFR part 195 is amended as follows:

PART 195—RADON PROFICIENCY PROGRAMS

1. The authority citation for part 195 continues to read as follows:

Authority: 15 U.S.C. 2665.

Subpart B—Fees

2. Section 195.20 is revised to read as follows:

§ 195.20 Fee payments.

(a) *Fee Amounts.* Applicants to and participants in the RMP and RCP programs shall pay fees according to the following fee schedule:

(1) *Organizations Listed for or Seeking Listing for Primary Measurement Services in the RMP Program.*

(i) In order to remain a listed participant, each organization that is listed for primary measurement services in the RMP program on the effective date of this section shall pay an annual fee of $390 for each device.

(ii) Each organization seeking listing for primary measurement services that submits an initial application after the effective date of this section shall pay an annual fee of $390 per device. This fee will be prorated quarterly, based on the acceptance date of an organization's application.

(iii) Organizations that have or are seeking a listing for secondary measurement services for their primary devices will not be required to pay the additional $50 fee applicable to secondary organizations.

(2) *Organizations Listed for or Seeking Listing for Secondary Measurement Services in the RMP Program.*

(i) In order to remain a listed participant, each organization that is listed for secondary measurement services in the RMP program on the effective date of this section shall pay an annual fee of $50 for each business location listed.

(ii) Each organization seeking listing for secondary measurement services that submits an initial application after the effective date of this section shall pay an annual fee of $50 for each business location listed. This fee will be prorated quarterly, based on the acceptance date of an organization's application.

(iii) Primary organizations that have or are seeking secondary listings for methods other than those for which they are listed as a primary, are subject to the fees.

(3) *Individual Proficiency Component of the RMP Program.*

(i) In order to remain a listed participant, each individual listed in the RMP individual proficiency program on the effective date of this section shall pay an annual fee of $105.

(ii) Each individual who submits an initial application after the effective date of this section shall pay an annual fee of $105. This fee will be prorated quarterly, based on the acceptance date of an individual's application.

(iii) Individuals who have or are seeking listing status as an RMP primary or secondary organization are subject to the applicable fees under paragraphs (a)(1) and (2) of this section.

(4) *RCP Program.*

(i)(A) In order to remain a listed participant, each individual listed in the RCP program on the effective date of this section shall pay an annual fee of $210.

(B) Each individual who is not a listed participant in the RCP program on the effective date of this section and submits an initial application after the effective date of this section shall pay an annual fee of $210. This fee will be prorated quarterly, based on the acceptance date of an individual's application.

(ii) An organization or individual who is not a listed participant in EPA's radon proficiency programs on the effective date of this section and/or whose proficiency program application has not yet been accepted by EPA becomes subject to the fees described above once its application has been accepted by EPA. Fees for such organizations or individuals will be prorated quarterly, based on the acceptance date of the application. To remain listed, each participant in the RMP or RCP programs, whether individual or organization, shall submit the appropriate annual fee to EPA each year.

(b) *Exemptions.* State and local governments are exempted from these fees under section 305(e)(2) of TSCA, 15 U.S.C. 2665.

(c) *Determination of Fees.* (1) Participants listed in the RMP and RCP programs on the effective date of this section will be sent, by EPA, a payment invoice with its fee calculation at least 30 days before the payment is due. Fees will be assessed based on the current information in EPA's proficiency data bases. Participants who intend to pay the invoiced fee amount must send their payment to EPA following the procedures in the invoice. Organizations or individuals who wish to notify EPA of any errors or corrections they wish to make to their listing status must do so by following the instructions on the payment invoice. Corrected payment invoices for both the RMP Program and the RCP Program shall be sent to: Radon Proficiency Programs User Fees, c/o Sanford Cohen and Associates, Inc. (SC&A), 1418 I–85 Parkway, Montgomery, Alabama, 36106. EPA will review the corrections noted on the payment invoice, adjust the payment invoice amount (as appropriate) and issue a new invoice. Participants must pay the amount in the corrected payment invoice within 30 days of the date listed on the corrected invoice.

(2) If the appropriate fee or a revised payment invoice for an individual or organization participating in the RMP or RCP program has not been received by EPA on or before the payment due date, EPA will send, by certified mail, notice that the individual or organization will be delisted from the proficiency program unless he/she pays the fee within 30 days of this second certified notification. If payment still has not been received by EPA after 30 days of the second certified notification, the organization's or individual's listing shall be removed from the proficiency program.

(3) New or initial applicants to the RMP or RCP programs will be assessed a fee at the time of their initial application. EPA will send a payment invoice to the new applicant upon acceptance of the initial application. The applicant will be given at least 30 days from the date on the payment invoice to remit payment. The fee assessed will be prorated quarterly, based on the acceptance date of the application. If the appropriate fee has not been received by EPA by the payment due date, the application will be placed in an inactive file with no further action taken by EPA.

(d) *Payment Procedures.* Each remittance to EPA under this section shall be in United States currency and shall be paid by certified check, personal or business check, or money order made payable to the order of the ''U.S. ENVIRONMENTAL PROTECTION AGENCY'' and sent to: U.S. EPA, Washington Financial Management

Center, Radon Proficiency Program User Fees (IRAA), P.O. Box 952491, St. Louis, Missouri, 63195–2491. The fee payment shall include the original copy of the EPA payment invoice. Collection of fees will begin in the calendar year beginning January 1, 1995. Specific guidance on how and when fees must be paid can be found in How to Pay Your Radon Proficiency Programs User Fees, U.S. EPA/Office of Radiation and Indoor Air. Copies of this document can be obtained by contacting the RIS at (334) 272–2797 or by FAX at (334) 260–9051.

(e) *Adjustment of Fees.* (1) EPA shall collect 100 percent of its operating costs associated with its radon proficiency programs by calendar year 1998. As necessary, EPA shall adjust the fees established by this subpart each year over the next four years to collect the following percentages of program costs:

Year 1	Year 2	Year 3	Year 4	Year 5
30%	47.5%	65%	82.5%	100%

Actual fees for each fiscal year will be calculated based on program costs and participation rates. New fee schedules will be published in the **Federal Register** as a technical amendment final rule to this part to become effective 30 days or more after publication.

(2) EPA will use a three-step process to adjust the fees annually. First, EPA will estimate the costs of providing each of the proficiency programs for the upcoming year. EPA will account for future additional fixed costs (e.g., updating examinations) and increases/decreases in variable costs due to inflation and other factors. In order to calculate increases/decreases in costs due to inflation, EPA may use one of the three following indices: the Federal General Schedule (GS) pay scale, the Consumer Price Index (CPI), and/or a component of the CPI, such as services. Second, EPA will estimate the number of participants for each program. At a minimum, these participation rates will be based on past and current program participation rates. Third, EPA shall calculate the per capita costs that individuals and organizations should pay to enable it to recover its fixed and variable costs each year for each program. EPA shall also consider potential industry impacts as it adjusts to levels to ultimately achieve full cost recovery over the period of five years.

[FR Doc. 95–20008 Filed 8–11–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 261

[FRL–5276–3]

Hazardous Waste Management System: Carbamate Production, Identification and Listing of Hazardous Waste

AGENCY: Environmental Protection Agency.

ACTION: Interpretative rule.

SUMMARY: The Environmental Protection Agency is today announcing a change in the Agency's interpretation of its rule that lists wastes from carbamate production as hazardous wastes under the Resource Conservation and Recovery Act (RCRA). Under this new interpretation, wastes from the production of non-carbamate intermediates that are used exclusively in the production of carbamates but are not produced at the ultimate site of manufacture of the carbamates will not be subject to the rule. These wastes are among those given the RCRA waste code designations K–156 and K–157 in the rule.

EFFECTIVE DATE: August 8, 1995.

ADDRESSES: The official record for this interpretative rule is identified as Docket number F–95–CPLF–FFFFF and is located in the RCRA Docket, Room M2616 (5305), 401 M Street, SW, Washington, DC, 20460. The public may make an appointment in order to review docket materials by calling (202) 260–9327. The docket is open for inspection from 9 AM to 4 PM, Monday through Friday, excluding Federal holidays. The public may copy material from any regulatory docket at a cost of $0.15 per page.

FOR FURTHER INFORMATION CONTACT: For general information contact the RCRA/Superfund Hotline, toll free, at (800) 424–9346, or at (703) 920–9810. For technical information concerning this notice, contact Mr. John Austin, Office of Solid Waste (5304), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC, 20460, (202) 260–4789.

SUPPLEMENTARY INFORMATION:

I. Background

On February 9, 1995 (60 FR 7824), EPA promulgated regulations under RCRA that listed as hazardous wastes six wastes generated during the production of carbamates and 58 commercial chemical products that become hazardous wastes when they are discarded or intended to be discarded. This rule becomes effective on August 9, 1995.

Among the six wastes subject to the rule are those designated by EPA as K–156 and K–157. The K–156 listing consists of ''[o]rganic waste (including heavy ends, still bottoms, light ends, spent solvents, filtrates, and decantates) from the production of carbamates and carbamoyl oximes'' (60 FR 7849, to be codified at 40 CFR 261.32). This waste was listed because it contains one or more of the following hazardous constituents of concern: formaldehyde, methylene chloride, triethylamine, carbofuran, benomyl, carbendazim, carbaryl, or carbosulfan (60 FR 7853, to be codified in Appendix VII to 40 CFR Part 261).

The K–157 listing consists of ''[w]astewaters (including scrubber waters, condenser waters, washwaters and separation waters) from the production of carbamates and carbamoyl oximes'' (60 FR 7849, to be codified at 40 CFR 261.32). This waste was listed because it contained one or more of the following hazardous constituents of concern—carbon tetrachloride, formaldehyde, methyl chloride, methylene chloride, pyridine, or triethylamine (60 FR 7853, to be codified in Appendix VII to 40 CFR Part 261).

Public comments on the proposed rule requested that EPA clarify the definition of carbamate ''production,'' principally to ensure that production would not include operations that isolate non-carbamate product for which there is otherwise a commercial market. In response to these comments, EPA set out its interpretation of the definition of production for purposes of the carbamate listing rule in the preamble to the final rule at 60 FR 7830.

After considering the comments and examining the industry, EPA concluded that carbamate production for purposes of the rule begins with the synthesis of non-carbamate chemicals that have no other use except for the production of a carbamate product. These non-carbamate chemicals are known as chemical ''intermediates'' in the industry. The consequence of this interpretation is that wastes generated from the manufacture of these

intermediates would be considered to be within the scope of the listing.

In its preamble interpretation, the Agency stated that processes that produce non-carbamate products which may be used in carbamate production, but have other uses, are not included in the definition of carbamate production. These latter processes would include production of phosgene and methyl isocyanate.

However, EPA also interpreted carbamate production to include manufacture of the non-carbamate intermediates used exclusively in carbamate production regardless of whether the manufacture occurred at the ultimate site of manufacture of the carbamate chemical. EPA specifically cited, as examples of these off-site intermediates—bendiocarb phenol, A–2213 (an intermediate in oxamyl production), and carbofuran phenol. 60 FR 7830.

A number of petitions for review challenging the carbamate listing have been filed in the United States Court of Appeals for the District of Columbia Circuit. These cases have been consolidated under the name, *Dithiocarbamate Task Force* v. *EPA*, Docket No. 95–1249.

As a result of settlement discussions EPA has reexamined the rulemaking record and determined that it lacks support for the interpretation of ''production'' as including manufacture of non-carbamate intermediates not produced at the ultimate site of carbamate production. In particular, information submitted by the producers of these non-carbamate intermediates shows that their wastes generated from manufacture of these intermediates do not contain any of the hazardous constituents of concern for which the K–156 and K–157 wastes have been listed. EPA has no other information to indicate that these waste streams contain any of these constituents.

Thus, EPA believes it has interpreted the definition of carbamate production in an overly broad manner to include wastes that should not be subject to the rule. Accordingly, EPA hereby changes its interpretation of carbamate ''production'' not to include non-carbamate intermediates that are produced at a site other than the ultimate site of carbamate production. Wastes from the production of such intermediates will not be covered by the listing.

II. Justification for Making the Interpretation Immediately Effective

EPA considers this change to its regulatory interpretation to be an interpretative rule exempt from the requirement for public notice and opportunity for comment procedures under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), because it informs the public of the Agency's views of how the term, ''production,'' in its own regulations will apply to carbamate waste listings. Also, EPA does not consider that this interpretation is subject to the requirements of the APA (5 U.S.C. 553(d)) or RCRA (section 3010(b); 42 U.S.C. 6930(d)) to delay the effective date of regulations after they are promulgated.

To the extent it may be argued that EPA is required to provide public notice and opportunity to comment or delay in the effective date, the Agency finds that good cause exists not to apply these procedures. If either notice and comment or delayed effective date procedures were applied, the off-site non-carbamate waste streams would become subject to the requirements of RCRA Subtitle as of August 9. The Agency has determined that this would be unfair, since EPA's rulemaking record indicates that the risks from these wastes are not significant and that the record does not support regulating them. Given the likelihood that the risks appear to be insignificant, at least to the extent they are examined in the rulemaking record, the wastes should not be subjected to the extensive requirements of the RCRA waste management regulations.

Dated: August 8, 1995.

Carol M. Browner,

Administrator.

[FR Doc. 95–20002 Filed 8–11–95; 8:45 am]

BILLING CODE 6560–50–M

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40 CFR Part 271

[FRL–5276–5]

Alabama; Final Authorization of Revisions to State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency.

ACTION: Immediate final rule.

SUMMARY: Alabama has applied for final authorization of revisions to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). Alabama's revisions consist of the ''Burning of Hazardous Waste in Boilers and Industrial Furnaces'' (BIF) provision and provisions contained in RCRA Cluster III. These requirements are listed in Section B of this notice. The Environmental Protection Agency (EPA) has reviewed Alabama's applications and has made a decision, subject to public review and comment, that Alabama's hazardous waste program revisions satisfy all of the requirements necessary to qualify for final authorization. Thus, EPA intends to approve Alabama's hazardous waste program revisions. Alabama's applications for program revisions are available for public review and comment.

DATES: Final authorization for Alabama's program revisions shall be effective October 13, 1995 unless EPA publishes a prior **Federal Register** action withdrawing this immediate final rule. All comments on Alabama's program revision applications must be received by the close of business, September 13, 1995.

ADDRESSES: Copies of Alabama's program revision applications are available during 8:00 am to 4:30 pm at the following addresses for inspection and copying: Alabama Department of Environmental Management, 1751 Congressman W. L. Dickinson Drive, Montgomery, Alabama 36109–2608. (334) 271–7700; U.S. EPA, Region 4, Library, 345 Courtland Street, NE, Atlanta, Georgia 30365; (404) 347–4216. Written comments should be sent to Al Hanke at the address listed below.

FOR FURTHER INFORMATION CONTACT: Al Hanke, Chief, State Programs Section, Waste Programs Branch, U.S. EPA Region 4, 345 Courtland Street, NE, Atlanta, Georgia 30365; (404) 347–2234.

SUPPLEMENTARY INFORMATION:

A. Background

States with final authorization under Section 3006(b) of the Resource Conservation and Recovery Act (''RCRA'' or ''the Act''), 42 U.S.C. 6926(b), have a continuing obligation to maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal hazardous waste program. In addition, as an interim measure, the Hazardous and Solid Waste Amendments of 1984 (Public Law 98–616, November 8, 1984, hereinafter ''HSWA'') allows States to revise their programs to become substantially equivalent instead of equivalent to RCRA requirements promulgated under HSWA authority. States exercising the latter option receive ''interim authorization'' for the HSWA requirements under Section 3006(g) of RCRA, 42 U.S.C. 6926(g), and later apply for final authorization for the HSWA requirements. Revisions to State hazardous waste programs are necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most

commonly, State program revisions are necessitated by changes to EPA's regulations in 40 CFR Parts 260–268 and 124 and 270.

B. Alabama

Alabama initially received final authorization for its base RCRA program effective on December 22, 1987. Alabama received authorization for revisions to its program on January 28, 1992, July 12, 1992, December 21, 1992, May 17, 1993, November 23, 1993, April 4, 1994, and January 13, 1995.

On November 12, 1993, and March 27, 1995, Alabama submitted program revision applications for additional program approvals. Today, Alabama is seeking approval of its program revisions in accordance with 40 CFR 271.21(b)(3).

EPA has reviewed Alabama's applications and has made an immediate final decision that Alabama's hazardous waste program revisions satisfy all of the requirements necessary to qualify for final authorization. Consequently, EPA intends to grant final authorization for the additional program modifications to Alabama. The public may submit written comments on EPA's immediate final decision up until September 13, 1995.

Copies of Alabama's applications for these program revisions are available for inspection and copying at the locations indicated in the ''Addresses'' section of this notice. Approval of Alabama's program revisions shall become effective October 13, 1995, unless an adverse comment pertaining to the State's revisions discussed in this notice is received by the end of the comment period.

If an adverse comment is received EPA will publish either (1) a withdrawal of the immediate final decision or (2) a notice containing a response to comments which either affirms that the immediate final decision takes effect or reverses the decision.

EPA shall administer any RCRA hazardous waste permits, or portions of permits that contain conditions based upon the Federal program provisions for which the State is applying for authorization and which were issued by EPA prior to the effective date of this authorization. EPA will suspend issuance of any further permits under the provisions for which the State is being authorized on the effective date of this authorization.

Alabama is today seeking authority to administer the following Federal requirements promulgated on February 21, 1991, for BIF and July 1, 1992–June 30, 1993, for RCRA Cluster III.

Federal requirement	FR reference	FR promulgation date	State authority
Checklist 85, Burning of Hazardous Waste in Boilers and Industrial Furnaces.	56 FR 7134	2/21/91	335–14–1–.02(1)(2), 12 & 13 335–14–2–.01(2)(d), 2(d),3(4)(b),4(b),7(b),8 335–14–2–.01(6)(a)3.(vii),(viii) 335–14–5–.7(3)(d)1 335–14–5–.15(1)(a) 335–14–6–.07(3)(a)(d)1(d)2 335–14–6–.07(4)(a) 335–14–6–.07(4)(b) 335–14–6–.15(1)(a) 335–14–7–.04(1)(6) 335–14–7–.08(1)–(13) 335–14–7-Appendix I–X 335–14–8–.02(13)(a)1,(a)1.(i),(ii)(a)2.(i),(ii) 335–14–8–.02(a)2(ii)(I)–(V) 335–14–8–.02(a)3,(a)3.(i)–(vii) 335–14–8–.02(13)(a)5,(a)5.(i)–(vii),(a)6,(a)6. (i),(a)6.(i)(I–III),(ii) 335–14–8–.02(13)(b),(b)1–6 335–14–8–.02(13)(c)(d)(e)(f) 335–14–8–.04(3)(g),(g)1,(g)1.(i–v) 335–14–8–.04(3) 335–14–8–.06(5)(a)(b),(b)1,(b)1. (i–ii),(b)2,(b)3. (i–iii),(b)4,(c),(c)1,(c)1.(i–ii),(c)2,(c)2.(i–viii),(c)4–9,(d)1–5,(e),(f),(f)1,(f)2,(f)2.(i–iii),(f)3–8 335–14–8–.07(3)(a)6,(b)7 335–14–8–.07(4)(f)(g)
Checklist 107, Used Oil Filter Exclusion; Technical Corrections.	57 FR 29220	7/1/92	335–14–2–.01(4)(b)13
Checklist 108, Toxicity Characteristic Revisions; Technical Corrections.	57 FR 30657	7/10/92	335–14–2–.01(4)(b)6.(ii),(b)9
Checklist 109, Land Disposal Restrictions for Newly Listed Wastes and Hazardous Debris.	57 FR 37194	8/18/92	335–14–1–.02(1) 335–14–2–.01(3)(c)2.(ii)(III),(3)(e),(e)1,(e)2 335–14–3–.03(5)(a)1.(iii),(a)1(iii) (II),(a)1.(iv),(iv)(I),(II),(5)(a)2 335–14–5–.07(1)(b)1–(b)4 335–14–5–.07(2)() 335–14–5–.07(3)(a)2 335–14–5–.08(1),(b)1–(b)4 335–14–5–.08(3)(a) 335–14–5–.30(1), (1)(a),(1)(b),(1)c,(1)c1–3,(1)(d)&(e) 335–14–5–.30(2)(a)2–4 335–140(2)(b),(2)(b)1,2,2.(i), (ii),(2)(b)3,(i),(i)(I)(II), (2)(b)4,(i–iii) 335–14.30(2)(c),(2)(c)1.(i–iv) 335–14–5–.30(2)(c)2,3,(i)(I–IV), (2)(c)3.(ii),(iii), (2)(c)4,(2)(d),(2)(d)1–3,(2)(e) 335–14–5–.30(3)(a)(b)

Federal requirement	FR reference	FR promulgation date	State authority
			335–14–6–.07(1)(b)1–4
			335–14–6–.07(2)(c)
			335–14–6–.07(3)(d)4
			335–14–6–.08(1)(b),(1)(b)1–3,(3)(a)
			335–14–6–.11(2)(h)
			335–14–6–.30(1),(1)(a)–(e)
			335–14–6–.30(2)(a),(2)(a)1,2,(2)(a)2(i), 2(ii),(2)(a)3&4 (2)(b),(2)(b)1,2,(2)(b)2.(i,ii)
			335.30(2)(b)3,(2)(b)3.(i), (I),(II)(ii)(iii),(2) (b)4, (i)(ii)(iii),(2)(c),(2) (c)1.(iiv),(2)(c)2,(2)(c)3,(i)
			335.14–6–.30(2)(c)3.(i)(I–IV),(2)(c)3. (ii)(iii),(2)(c)4, (2)(d)(2)(d)1–3,(2)(e), (3)(a),(3)(b)
			335–14–9–.01(2)(7)(9)
			335–14–9–.02(5)
			335–14–9–.03(7)
			335–14.04(1)(2)(3)(4)(6)(7)
			335–14–9–.05(1)
			335–14–9-Appendix II
			335–14–8–.02(4)(n)
			335–14–8–.02(b)2
			335–14–8–.04(3)(a)11
			335–14–8–.07(3)(b)6
Checklist 110, Coke By-Products Listings	57 FR 37284	8/18/92	335–14–2–.01(4)(a)10
			335–14–2–.04(3)
			335–14–2-Appendix VII
Checklist 111, Burning of Hazardous Waste in Boilers and Industrial Furnaces; Technical Amendment III.	57 FR 38558	8/25/92	335–14–1–.02(1)
			335–14–2–.01(2)(e)2.(iv)
			335–14–5–.01(1)(g)2
			335–14–6–.01(1)(c)6
			335–14–7–.08,(9)(c)(13)
			335–14–7–Appendix IX
Checklist 113 Consolidated Liability Requirements	57 FR 42832	9/16/92	335–14–5–.08(2)(h)
.....	53 FR 33938	9/1/88	335–14–5–.08(4)(f)10,11
.....	56 FR 30200	7/1/91	335–14–5–.08(8)(a),(8)(a)2–7(i)(ii)(iii)
			335–14–5–.08(8)(b),(8)(b)2–7(i)(ii)(iii)
			335–14.08(8)(f)7,8(g), (8)(g)1(ii),2.(i)(ii)
			335–14–5–.08(8)(h),(8)(h)1–5
			335–14–5–.08(8)(i).(8)(i)1–4,(8) (i)4(i)(ii),(8)(j),(8)(j)1 4,(8)(k)
			335–14.08(12)(b)(f)(g)(h)1,2
			335–14–5–.08(12)(i)2.(d)
			335–14–5–.08–(12)(j)2.(d)
			335–14–5–08(12)(k),(L), (m)1,2,(h)2,(n)n2
			335–14–6–.08(4)(e)10,ll
			335–14–6–.08(8)(a),(a)2–7(i–iii),(8)(b),(b)2–7(i–iii),(8)(f)6, (8)(g),(8)(g)1(i–ii),(8)(h),(8)(h)1–5,(8)(i),(8)(i)1–4, (8)(i)4.(i)(ii),(8)(j),(8)(j)1–4,(8)(k)
Checklist 114, Burning of Hazardous Waste in Boilers and Industrial Furnaces; Technical Amendment IV.	57 FR 44999	9/30/92	335–14–7–.08(4), Appendix IV
Checklist 115, Chlorinated Toluenes Production Waste Listing.	57 FR 47376	10/15/92	335–14–2–.04(3)
			335–14–2–Appendix VII
Checklist 118 Liquids in Landfills II	57 FR 54452	11/18/92	335–14–1–.02(1)
			335–14–5–.02(4)(c)4
			335–14–5–14(15)(a)(b)(d)1.(ii)(e)1.(ii–iii)(e)2.(i–ii)
			335–14–5–.14(17)(b)(c)
			335–14–6–.02(4)(c)4
			335–14–6–.14(15)(a)(b)(f)(f)1(f)1.(i–iii)(f)(i–ii)
			335–14–6–.14–(15)(g)(15)(g)1&2
			335–14–6–.14(17)(b)(c)
Checklist 119, Toxicity Characteristic Revision; TCLP Correction.	57 FR 55114	11/24/92	335–14–2–Appendix II
Checklist 120, Wood Preserving; Revisions to Listings and Technical Requirements.	57 FR 61492	12/24/92	335–14–2–.04(2)
			335–14–5–.23(1)(a)(1)(c,(1)(c)1,(1)(c)1.(i–iv)
			335–14–5–.23(2)(a)(2)(b)(2)(b)1–3
			335–14–5–.23(3),(3)(a),(3)(b), (4)(a)4.(i,ii)(4)(b),(4)(b)3, (4)(i)
			335–14–6–.23(1)(a)(1)(c)(1)(c)1.(i–iv)
			335–14–6–.23(2)(a)(b)(2)(b)1–3
			335–14–6–.23(3)(3)(a)(3)(b)(4)(a) 4.(i,ii),(4)(b),(4)(b)3.(4)(i)
Checklist 124, Land Disposal Restrictions for Ignitable and Corrosive Characteristic Wastes Whose Treatment Standards Were Vacated.	58 FR 29860	5/24/93	335–14–5–.01(1)(g)6
			335–14–6–.01(1)(c)10
			335–14–9–.01(1)(2)(7)(9)
			335–14–9–.03(8)

Federal requirement	FR reference	FR promulgation date	State authority
			335–14–9–.04(1)(2)(3)(4) 335–14–8–.04(3)(a)2

Alabama's applications for these program revisions meet all of the statutory and regulatory requirements established by RCRA. Accordingly, Alabama is granted final authorization to operate its hazardous waste program as revised.

Alabama now has responsibility for permitting treatment, storage, and disposal facilities within its borders and carrying out other aspects of the RCRA program, subject to the limitations of its program revision application and previously approved authorities. Alabama also has primary enforcement responsibilities, although EPA retains the right to conduct inspections under Section 3007 of RCRA and to take enforcement actions under Section 3008, 3013, and 7003 of RCRA.

Compliance With Executive Order 12866

The Office of Management and Budget has exempted this rule from the requirements of Section 6 of Executive Order 12866.

Certification Under the Regulatory Flexibility Act

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this authorization will not have a significant economic impact on a substantial number of small entities. This authorization effectively suspends the applicability of certain Federal regulations in favor of Alabama's program, thereby eliminating duplicative requirements for handlers of hazardous waste in the State. It does not impose any new burdens on small entities. This rule, therefore, does not require a regulatory flexibility analysis.

List of Subjects in 40 CFR Part 271

Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

Authority: This notice is issued under the authority of Sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act as amended (42 U.S.C. 6912(a), 6926, 6974(b)).

Dated: August 4, 1995.

John H. Hankinson, Jr.,

Regional Administrator.

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DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Part 192

[Docket PS–135; Amdt. 192–3]

RIN 2137–AC32

Customer-Owned Service Lines

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Final rule.

SUMMARY: This action requires operators of gas service lines who do not maintain buried customer piping up to building walls or certain other locations to notify their customers of the need to maintain that piping. Congress directed DOT to take this action in view of service line accidents. By advising customers of the need to maintain their buried gas piping, the notices may reduce the risk of further accidents.

EFFECTIVE DATE: September 13, 1995.

FOR FURTHER INFORMATION CONTACT: L. M. Furrow, (202) 366–2392, regarding the content of this document, or the Dockets Unit (202) 366–4453 for copies of this final rule or other material in the docket.

SUPPLEMENTARY INFORMATION:

I. Background

A. Customer Piping

RSPA's gas pipeline safety standards (49 CFR Part 192) apply to the distribution of gas up to the end of a pipeline operator's service line. A service line, as defined in § 192.3, is a distribution line that begins at a common source of supply, usually a main, transmission line, or gathering line. The end of a service line is a customer meter or a connection to a customer's piping, whichever is farther downstream. If there is no meter, the connection to a customer's piping marks the end of a service line. A customer is any person who contracts with an operator to receive gas for consumption. Customer's piping (or customer piping) refers to piping not owned by an operator through which a customer receives gas.

When operators install customer meters, they usually install them outdoors next to the building that houses the customer's principal gas utilization equipment. If that equipment is not inside a building, the meter may be installed next to the equipment. Either of these installations may leave only a short segment of exterior customer piping between the end of the operator's service line and the building or equipment. Sometimes, however, operators install customer meters farther away from buildings or equipment, perhaps at a private property line or fence. The result is a much longer length of exterior customer piping.

Regardless of length, customer piping downstream from an operator's service line is not subject to the maintenance standards of Part 192. However, according to the National Transportation Safety Board, twenty-two states now require operators to monitor portions of customer piping. Also, many operators voluntarily maintain customer piping up to building walls. Still, for much customer piping, maintenance is the responsibility of customers or piping owners, not operators of service lines. In this regard, RSPA is preparing a report on the safety of customer piping located downstream from service lines to see if there is a need for further legislative or regulatory action. The report is required by section 115(b) of the Pipeline Safety Act of 1992 (Pub. L. 102–508; 106 Stat. 3296).

B. Statutory Mandate

During a 7-month period beginning September 16, 1988, a series of five service line accidents killed four people and injured 16 others in Kansas and Missouri. The accidents happened on service lines supplying gas to homes and were due to corrosion and other causes. As a result, Congress became concerned about the safety of gas piping leading up to buildings. Congress felt that customers of distribution pipeline operators may not understand the need for basic maintenance of customer piping.

Therefore, as provided by 49 U.S.C. § 60113(a) (formerly section 18(b) of the

Natural Gas Pipeline Safety Act of 1968), Congress directed DOT to—

Prescribe regulations requiring an operator of a natural gas distribution pipeline that does not maintain customer-owned natural gas service lines up to the building walls to advise its customers of—

(1) the requirements for maintaining those lines;

(2) any resources known to the operator that could assist customers in carrying out the maintenance;

(3) information the operator has on operating and maintaining its lines that could assist customers; and

(4) the potential hazards of not maintaining the lines.

C. Rulemaking Proposal

In response to this Congressional mandate, RSPA published a notice of proposed rulemaking (NPRM)(59 FR 5168; February 3, 1994) on customer notification. The NPRM proposed to define the piping covered by the mandate (''covered piping''). The NPRM also proposed to establish the details of advice that operators who do not maintain covered piping up to building walls would have to give their customers.

In a supplemental notice of proposed rulemaking (SNPRM)(59 FR 13300; March 21, 1994), RSPA expanded the proposed rules to cover certain exterior customer piping that is above ground. The SNPRM also clarified that the proposed rules were not limited to operators who are local distribution companies. Other operators (primarily transmission companies) that supply gas to customers through service lines were covered as well. RSPA also announced in the SNPRM that the proposed rules did not apply to customer piping that branches from a customer's primary gas supply line to supply gas to secondary equipment, such as pool heaters and yard lanterns.

D. Advisory Committee Review

RSPA presented the NPRM and SNPRM for deliberation by the Technical Pipeline Safety Standards Committee (TPSSC) at a meeting in Washington, D.C. on May 11, 1994. TPSSC is RSPA's statutory advisory committee for gas pipeline safety. The committee comprises 15 members, representing industry, government, and the public, who are technically qualified to evaluate gas pipeline safety. TPSSC's report of its deliberation is available in the docket of this proceeding.

TPSSC voted unanimously to find the proposed rules technically feasible, reasonable, and practicable, provided RSPA made the following changes: (1) delete information on age, location, and material of customer piping from proposed § 192.16(a)(4); (2) when customer piping does not enter a building, end covered piping at the point of custody transfer; (3) apply the proposed rule only to buried residential and small-commercial lines; and (4) delete ''transmission or'' from proposed § 192.16(a) to limit the rule to distribution operators. The next section discusses how we handled TPSSC's recommended changes in developing the final rule.

II. Discussion of Comments and TPSSC Recommendations

A. Commenters

We received written comments from 57 persons in response to the NPRM and SNPRM. The comments came from: 47 pipeline operators; 5 state pipeline safety agencies (Maryland, Kansas, Iowa, Michigan, and Missouri); 4 trade associations (American Gas Association (AGA), Interstate Natural Gas Association of America (INGAA), Western Mobilehome Parkowners Association (WMPA), and Texas Gas Association (TGA)); and 1 federal agency (National Transportation Safety Board (NTSB)).

Most commenters directed their remarks to specific issues. This section of the preamble discusses our resolution of significant issues in light of comments and TPSSC recommendations.

B. The Term ''Customer-Owned Service Line''

The mandate applied to customer piping Congress called ''customer-owned service lines.'' So the NPRM and SNPRM used this term to designate the customer piping covered by the proposed rules.

Despite its statutory origin, many commenters felt the term ''customer-owned service line'' would be confusing in a Part 192 regulation. They said many service lines under Part 192 include piping owned by customers. Consequently, they argued the term was too similar to ''service line'' to distinguish customer piping not regulated by Part 192 from service lines regulated by Part 192. The commenters suggested as alternatives the names ''supply pipe,'' ''yard line,'' ''fuel line,'' and ''customer-owned piping.''

We agree that ''customer-owned service line'' would be a misnomer in Part 192. The term could easily be confused with ''service line,'' because some customers own the portion of a service line on private property between a distribution main and customer meter. Also, other customers (particularly tenants) may not own any of the piping through which they receive gas from an operator. For these reasons, we did not use the term ''customer-owned service line'' in the final rule.

At the same time, we did not name covered piping as commenters suggested. Since Part 192 currently refers to piping beyond the end of a service line as ''customer's piping'' (see § 192.3, service line), referring to that piping by another name would be confusing. Instead, to designate piping covered by the final rule, we used ''customer's piping'' with other descriptive wording (§ 192.16(a)).

C. End of Covered Piping

To delineate the customer piping covered by the proposed rules, the NPRM and SNPRM defined the term ''customer-owned service line.'' The definition proposed was: ''a pipeline that transports natural gas or petroleum gas from a service line to (1) an exterior wall of a building, or (2) end-use equipment'' (proposed amendment to § 192.3).

Most commenters thought the proposed end of covered piping was unclear. One concern was the end of covered piping when customer piping leads to more than one building. Another concern was the end when customer piping leads both to a building and to outdoor equipment, such as a lantern. Still another concern was the end when customer piping does not enter a building, which happens at some plants. In regard to plants, AGA argued the end should be at a location equivalent to a building wall, such as the plant fence or point of custody transfer. Similarly, TPSSC recommended ending covered piping at a custody transfer point when there is no building.

As stated above, we intended the proposed rules to apply to customers' primary gas supply lines. Branch lines that serve pool heaters, yard lanterns, or other types of secondary equipment were not intended to be covered. The final rule (§ 192.16(a)) clarifies this point by covering customer piping up to gas utilization equipment only when the customer's piping does not enter a building. Also, to avoid the confusion of where covered piping ends when customer piping enters more than one building, the final rule refers to the first building. We used the term ''gas utilization equipment'' instead of ''end-use equipment'' for consistency with present terminology in Part 192 (e.g., § 192.197(a)(5)).

When customer piping does not enter a building, we agree that a perimeter fence (or wall) surrounding the gas utilization equipment serves the

purpose of a building wall under the mandate. Thus, when there is no building, under the final rule, covered piping ends at the gas utilization equipment or at the intersection of the first fence (or wall) that encloses the equipment (if such a fence (or wall) exists). The fence (or wall) may surround the plant, part of the plant, or just the equipment.

We did not adopt custody transfer to demarcate the end of covered piping when customer piping does not enter a building. Because custody transfer arguably occurs when gas enters piping not owned by the operator, none of the customer piping downstream from a service line would come under the notification rule.

D. Aboveground Customer Piping and Short Sections of Piping Between Meters and Buildings

Many commenters, including AGA and Missouri, recommended that the final rule apply only to buried piping. Generally, the commenters felt that aboveground piping presents less risk than buried piping. The commenters said operators or customers would see any deteriorated piping or they would smell any leaks. Further, the commenters envisioned that any leaks would go directly to the atmosphere and not migrate into a building. TPSSC also recommended that we limit the final rule to buried piping.

The chief reason, however, that most commenters wanted to restrict the final rule to buried piping was to reduce the number of customers that would have to be notified. This point was emphasized by AGA at the TPSSC meeting, convincing TPSSC to overturn an earlier vote against excluding aboveground piping. Millions of additional customers would have to be notified if aboveground piping were covered, since most service lines, including lines that end at meters next to buildings, connect to short sections of aboveground piping. For example, one operator said it would have to send 1.3 million notices if the rule covered aboveground piping, compared with 68,000 notices if only buried piping were covered. This operator argued that since the accidents that produced the mandate all involved buried piping, Congress did not intend the mandate to cover aboveground piping. In addition, according to WMPA, if the rule covered aboveground short sections of piping, it would affect most of the 2,950 mobilehome parks in California with master meter systems. WMPA said mobilehomes in these parks are usually connected to gas meters by short flexible pipe that is the responsibility of the mobilehome owner. WMPA recommended that the final rule not apply to aboveground piping less than 6 feet long.

We too were concerned about the impact of the proposed rules on short sections of piping between customer meters and buildings. So, in the NPRM and SNPRM, we asked for public comment on whether these short sections of piping are properly installed and periodically maintained. One operator commented that trained operator or heating contractor personnel install the short sections. Another operator said installation is done according to the National Fuel Gas Code, interior gas piping standards produced by the American National Standards Institute and the National Fire Protection Association. Several operators said that short sections seldom or never leak. A few operators reported they periodically inspect short sections for leaks and advise customers of any problems. However, one operator said it does not check commercial or industrial piping. Two other operators said they check for leaks when they turn gas on or when they receive leak reports. WMPA commented that leak surveys normally include the customer's connector pipe, and that mobilehome owners are advised of any needed repairs.

These comments and the TPSSC recommendation convinced us that aboveground customer piping should not be regarded as covered piping. First of all, we recognize that if aboveground piping were covered, almost every gas customer in the U.S. would have to be notified. And there is no evidence that a notification program of this magnitude would result in a comparable increase in public safety. Nor do we think Congress contemplated a huge, nationwide notification program. Although the mandate arguably applies to any customer piping up to building walls, the fact that the accidents that led to the mandate happened on buried service lines means it is reasonable to conclude that Congress intended the mandate to cover only buried customer piping. This conclusion is congruous with the risks involved, because as the comments indicate, aboveground customer piping poses much less risk than buried customer piping. Therefore, the final rule applies only to buried piping (§ 192.16(a)). As a result, short sections of customer piping between customer meters and building walls that are entirely aboveground are not covered by the final rule.

E. Farm Taps and Industrial Taps

The proposed rules applied to customers served by ''farm taps'' or ''industrial taps.'' Farm tap is industry jargon for a pipeline that branches from a transmission or gathering line to deliver gas to a farmer or other landowner. Similarly, an industrial tap is a pipeline that branches from a transmission or gathering line to deliver gas to an industrial plant. So companies primarily engaged in the transmission or gathering of gas operate most farm taps and industrial taps.

About a third of commenters argued against this proposal, saying that Congress intended the mandate to apply only to local distribution companies. In support, they pointed out that residential accidents prompted the mandate. They also said that customers served by farm and industrial taps are more likely than residential customers to be familiar with the need to maintain gas piping. In this regard, a gas production company said its lease agreements with farm tap customers make them aware of their responsibility for maintenance. TPSSC also recommended that we limit the final rule to distribution operators and to residential and small commercial customers.

We do not believe these arguments and TPSSC recommendations justify excluding farm tap and industrial tap customers from the final rule. To begin with, while we recognize that Congress was primarily concerned about residential customers, the mandate is not so limited. Congress applied the mandate to ''operators of natural gas distribution pipelines.'' But these operators are not just local distribution companies as the commenters suggested. Some operators primarily engaged in the gathering or transmission of gas also operate distribution pipelines. They do so when they deliver gas directly to customers through farm taps and industrial taps. In fact, because portions of these delivery lines qualify as service lines, gathering and transmission operators report them as distribution pipelines under 49 CFR 191.13. Moreover, farm and industrial tap customers are not immune from harm by potential hazards that could occur on their piping. And surely not all farm and industrial tap customers know enough about gas piping safety to make even a single maintenance notice unnecessary.

Therefore, application of the final rule does not depend on the nature of an operator's primary business. To clarify this point, we reworded the final rule (§ 192.16(a)) so that it applies to operators of service lines, instead of transmission or distribution operators as proposed. Although this change made it unnecessary to define ''farm tap'' or

''industrial tap,'' operators of these taps are not excepted from the final rule.

We recognize that local distribution companies operate some metered farm taps on transmission lines. In these cases, the local distribution company is responsible for compliance with the final rule.

F. Meaning of ''Maintain''

The mandate applies to operators who do not ''maintain'' customer piping up to building walls. What Congress meant by ''maintain'' is important, because operators who maintain customer piping up to building walls need not advise customers of the need for maintenance. Because ''maintain'' is inexact, the NPRM and SNPRM proposed to clarify the mandate by giving ''maintain'' a particular meaning: ''maintain * * * to Part 192 standards'' (proposed § 192.16(a)).

Commenters thought the standards in Part 192 were not an appropriate gauge of whether an operator maintains covered piping as Congress had in mind. One operator put it this way: while it may be reasonable to conduct a leakage survey every 3 years (under § 192.723) up to the nearest building wall and, if a leak is detected, shut off the flow of gas, it would not be reasonable to maintain a customer's piping to meet all Part 192 maintenance standards. Another operator thought the proposal was unreasonable because it would require operators to send notices to customers even if operators maintain covered piping according to State requirements, but not to Part 192.

RSPA agrees that operators would have difficulty meeting Part 192 maintenance standards on covered piping. Operators may lack permission from property owners to take maintenance action or lack the necessary information upon which to base maintenance action. For example, under § 192.725, each disconnected service line must be pressure tested as a new line. Yet operators probably would need access to the customer's building and other permission from the customer or property owner to do this test on a customer's piping. Another example is § 192.455(a), which provides that each buried pipeline installed after July 31, 1971, must be protected against external corrosion. This regulation presumes operators know the installation date of their pipelines, a fact they may not know for a customer's piping.

Upon further consideration, we are defining ''maintain'' to mean whatever maintenance is reasonable for operators to do on covered piping, considering the Congressional intent. Although the legislative history casts little light on what Congress meant by ''maintain,'' it does show that Congress was concerned about corrosion-related accidents on service lines.

Preventing and correcting hazardous leaks are the major safety reasons to maintain gas pipelines. The comments show that many operators already check customer piping between customer meters and building walls for leaks. Some operators may check for leaks while doing routine leakage surveys on their own pipelines under § 192.723. If a leak is found, depending on the nature of the leak, they either shut off the flow of gas or warn the customer to repair the leak.

Besides leakage checks, another reasonable maintenance activity is to monitor customer piping for corrosion, a major cause of leaks on metallic pipelines. More specifically, operators must periodically monitor their buried metallic service lines for external corrosion under § 192.465. With permission from the land owner or tenant, operators could also monitor covered piping according to this standard. However, rather than take the specified remedial action, which might be difficult to do on covered piping, they could shut off the flow of gas or warn the customer to repair any harmful corrosion found.

Considering the reasons for maintenance, Congress's concern about corrosion, present industry practices, and commenters' advice, we believe ''maintain'' means periodic checking for leaks and corrosion, with appropriate follow-up action. Thus, the final rule (§ 192.16(a)) provides that operators who do not maintain covered piping according to § 192.465 (if applicable) and § 192.723, with appropriate remedial action, must send the customer a maintenance notice.

In accordance with Executive Order 12898 on Environmental Justice, we have considered the potential effect of this final rule on minority and low income customers. Because the rule applies only to gas operators who do not inspect certain customer piping, the rule will not impose direct costs on gas customers. However, some customers may incur indirect costs of the rule. Customers who own exterior gas piping and decide to heed the gas company's maintenance advice could face large repair bills, depending on the condition and amount of their piping. Indirect costs can also arise when operators who inspect customer-owned piping discover that it is leaking or otherwise unsafe and require customers to repair the piping if gas service is to continue.

We cannot predict which customers would be likely to incur these indirect costs. However, the proportion of minority and low income customers that might incur them should be small, because most minority and low income gas customers are tenants. As tenants, they can reasonably be expected to refer the matter of piping maintenance or unsafe piping to their landlords, who are responsible for corrective action.

When minority and low income customers must bear the indirect costs themselves, voluntary organizations and local welfare agencies can reasonably be expected to provide assistance, especially in response to gas shut off situations if the health of customers is affected. In addition, we expect that states adopting this final rule will monitor its effect on minority and low income gas customers and find additional ways to lessen the indirect cost burden. For example, states may require operators to stand the cost of maintenance or establish a fund to pay for maintenance that minority and low-income customers cannot afford.

Despite the potentially low impact of this final rule on minority and low income customers as a whole and efforts to defray indirect costs, the cost of piping maintenance will unavoidably be a hardship for some minority and low income customers. Still, in view of the high safety risk of deteriorating residential gas piping and Congress's mandate that operators warn customers about this potential problem, we see no federal regulatory alternative that would lessen the potential cost burden. We will, however, examine this issue further in the report to Congress on the safety of customer-owned service lines that is required by section 115(b) of the Pipeline Safety Act of 1992 (Public Law 102–508, 106 Stat. 3296).

G. Customer Responsibility

The NPRM and SNPRM proposed that operators who do not maintain covered piping must notify the customer that ''the customer owns and is responsible for the maintenance of the customer-owned service line'' (proposed § 192.16(a)(1)). The purpose of this proposal was to alert customers that the operator does not maintain the customer's piping.

AGA and several operators pointed out that customers who occupy rental properties, especially commercial buildings, may not own the piping through which they receive gas. Other commenters observed that operators may not know who owns the customer's piping. One solution a commenter suggested was that the notice advise

rental customers to refer the maintenance advice to the landlord.

Another consideration, not raised by commenters, is that many states now require operators to do some maintenance on customer piping. In these states, it would be incorrect for operators to notify customers that the customers or their landlords are responsible for maintenance of customer piping.

Thus, it appears the proposal could be confusing or incorrect in some circumstances if included in maintenance notices. To avoid this confusion, the final rule (§ 192.16(b)(1)) merely requires operators to notify customers that the operator does not maintain the customer's piping.

Some operators may do a level of maintenance on customer piping (either voluntarily or under State law) that does not reach the minimum level prescribed by the final rule. If these operators wish to avoid advising customers that they do not maintain customer piping, they would have to increase their maintenance to the minimum level.

H. Requirements for Maintenance

Under the mandate, operators who do not maintain covered piping must advise their customers of the requirements for maintenance of that piping. To carry out this feature of the mandate, the NPRM and SNPRM proposed that operators notify customers ''of the essential elements for proper maintenance * * * such as those listed in subpart M of [Part 192] or those listed in applicable local building codes'' (proposed § 192.16(a)(2)).

Many commenters, including Iowa, Michigan, AGA, and TGA, recommended that the final rule not refer to Part 192 or local codes as examples of the essential elements of maintenance. The objection expressed most often was that Subpart M of Part 192 is not appropriate for customer piping downstream from meters; it was written for operators, not customers. Commenters also said the proposed rule was indefinite about which sections in Subpart M to apply to customer piping. Several commenters said that Subpart M and the local codes may conflict with each other, forcing operators to choose which standard is appropriate for customers to follow. One commenter stated it would be unreasonable to require operators to learn the essential elements of local building codes applicable to maintenance of customer piping and then send that information to each customer. For example, one large distribution company said it would be especially burdensome to examine the details of local codes in the 535 cities, towns, and communities it serves, and to continually keep abreast of them.

Alternatively, INGAA and an operator suggested that the final rule specify the maintenance advice operators are to give customers, instead of leaving it to the operator's discretion. INGAA said this approach would minimize the potential liability for giving inappropriate advice. The operator said it would reduce the confusion of different operators giving different advice to similar customers. Two operators thought we should limit the maintenance advice to periodic leakage surveys. Also, two other operators advised us to mention corrosion control as an example of essential maintenance.

We believe Congress used the word ''requirements'' in the sense of actions that are necessary for maintenance, rather than required by law for maintenance. So we proposed that operators use local codes, Subpart M of Part 192, or other sources as a guide to identify essential elements of maintenance. Although many commenters interpreted the proposal to the contrary, we did not intend for operators to keep abreast of local code requirements applicable to maintenance of customer piping. Nor did we intend for notifications to bring customers up to date about their obligations under local law.

We recognize, though, that the proposed rules gave operators wide latitude to decide what maintenance advice to provide customers. We also recognize that confusion could result if operators gave different advice in similar situations. So we adopted the suggestion to specify essential maintenance advice. We based the specified maintenance advice on the recommendations of commenters and the decision discussed above on the meaning of ''maintain.'' Since the specified maintenance advice is commonly found in pipeline safety programs, we doubt it conflicts with local codes.

Consequently, the final rule (§ 192.16(b)(3)(i)–(iii)) does not require notice of any provisions of Subpart M of Part 192 or of any local code requirements. It simply requires operators to notify customers that their buried gas piping should be periodically inspected for leaks; periodically inspected for corrosion, if the piping is metallic; and repaired if any unsafe condition is found. By referring to buried piping, the notice will encourage customers to apply the advice to any buried piping they may have besides their primary supply line.

I. Maintenance Assistance

The mandate requires that operators advise customers of any resources known to the operator that could assist customers in carrying out maintenance. In response, we proposed that operators notify customers ''of available resources that could aid the customer in obtaining maintenance assistance, such as the gas pipeline operator, the state licensing board for plumbers and state plumbers' associations, Federal and state gas pipeline safety organizations, the local building code agencies, and appropriate leak detection, gas utility, and corrosion protection contractors'' (proposed § 192.16(a)(3)).

Many commenters said it would be too burdensome to maintain current lists of agencies, associations, and contractors over wide areas. They said customers could easily find maintenance assistance by consulting the local better business bureau or chamber of commerce. A few commenters were concerned the proposed rule would cause suits to be filed against the operator for unfair competition if notices omitted appropriate contractors, or for negligence if recommended contractors caused injuries or did unsatisfactory work. One commenter thought the proposed rule was unfair because it would force operators to refer customers to businesses that compete with the operators to provide maintenance services on gas piping.

In view of these comments, we decided to require operators to give only general advice about maintenance assistance. Operators need not maintain lists of specific contractors that might do maintenance work on customer piping. Although government agencies probably could advise customers about State or local laws, this advice probably would not be helpful in carrying out maintenance. Instead of advising inquirers about the details of maintenance, agencies and associations probably would refer them to contractors. Since customers can learn the names of contractors through the yellow pages or local chambers of commerce, the final rule does not require notice of specific contractors, agencies, or associations. The rule (§ 192.16(b)(5)) simply requires notice that the operator (if applicable), plumbers, and heating contractors may be contacted for assistance in maintaining and locating the customer's piping. Under this rule, if an operator does not offer such assistance, it would not have to mention itself as a possible source of assistance. At the same time, an operator may not mention only itself

as a source of assistance on customer piping.

J. Other Helpful Information

1. General

The mandate requires that operators provide information the operator has on operating and maintaining its lines that could assist customers. In turn, we proposed that operators notify customers of ''any information that the operator has concerning the operation and maintenance of the customer-owned service line that could aid the customer, such as information on excavation damage prevention, local codes and standards (when applicable), and the age, location, and material of the customer-owned service line'' (proposed § 192.16(a)(4)).

2. Age, Location, and Material

TPSSC and about a third of commenters urged us not to require operators to provide information about the age, location, and material of customer piping. Several commenters said that because the information was site specific, operators could not use a notice generally applicable to all customers, as contemplated in the NPRM. Others said operators typically do not have the proposed information about customer piping, and it would be an undue burden to get it. A number of commenters also pointed out that the age of customer piping may not correspond to the date the operator established gas service, because the customer may have replaced or altered the piping since that date.

We agree that operators may not have the proposed information about customer piping, since they are not required by Part 192 to maintain the piping. Also, obtaining the information would be a significant burden that Congress did not intend operators to assume. The mandate requires operators to give customers helpful information based on the operation and maintenance of the operator's pipelines. The mandate does not require operators to gather information about customer piping. Even when operators do have some information about customer piping, requiring them to add the information to notices might not allow the operators to use a general notice to meet the notification rule. Therefore, this final rule does not require operators to notify customers of the age, location, and material of customer piping.

As a result, operators may send each customer a notice on the proper maintenance of customer piping in general. Notices need not be tailored to meet specific customer situations. However, operators who have specific information about customer piping and wish to include it in notices are encouraged to do so.

3. Local Laws

For reasons discussed above concerning proposed § 192.16(a)(2), several commenters suggested that the final rule not make operators responsible for advising customers about local laws. Since local building codes would be burdensome for operators to track, are the responsibility of local agencies to enforce, and are unlikely to contain instructions on how to carry out piping maintenance, the final rule does not require notice of local laws.

4. Excavation Damage Prevention

Two operators asked us to clarify the information they would have to provide about excavation damage. They suggested the notice stress the need to locate piping before excavating and to dig with care.

We agree that this information would be helpful to customers, because of the large number of gas pipeline accidents attributable to excavation damage. The final rule (§ 192.16(b)(4)) reflects these comments. However, operators are not required to notify customers to contact ''one-call'' systems to learn the location of buried customer piping before excavating. One-call systems provide such service only for piping of companies that are members of the system. One-call systems generally have no information regarding customer piping.

Apart from the maintenance requirements discussed above, information about preventing excavation damage is probably the most significant information operators have about operating and maintaining their own pipelines that would be helpful to customers. In the interest of producing a general notice limited to basic advice, the final rule does not require notice of any other information related to operation and maintenance of the operator's pipelines. However, operators may supplement the required information as they deem appropriate.

K. Potential Hazards

The mandate requires that operators notify customers about the potential hazards of not maintaining customer piping. As proposed in the NPRM and SNPRM, operators would have to advise customers of ''the potential hazards of not maintaining the customer-owned service line, such as corrosion and gas leakage'' (proposed § 192.16(a)(5)).

Only a few commenters addressed this proposal. Two commenters thought it would be unfair if operators had to warn their customers that gas piping can be hazardous, while their competitors, fuel oil and electric companies, do not have to give a similar warning. One commenter said that sending notices about potential hazards would not be compatible with the goal of market expansion. Another commenter requested that in the final rule, we insert ''reasonably foreseeable'' before ''potential hazard.''

Although we do not have discretion under the mandate not to require notice of potential hazards, we did not find the arguments against such notice persuasive. The risks involved in using fuel oil and electricity have not demanded the same level of public attention as gas pipeline risks. So, from a public policy standpoint, it is not unfair if only gas pipeline operators must warn their customers of risks. Also, we do not agree that warning customers of potential hazards is incompatible with business expansion. Part 192 already requires operators to post signs over their pipelines warning of potential danger (§ 192.707), and to educate the public to recognize gas pipeline emergencies (§ 192.615). These programs and the abundant advertisements about using ''one call'' systems to guard against the hazards of excavation damage have, to our knowledge, not adversely affected the growth of business. Indeed, we believe people prefer to do business with socially responsible companies that do not hesitate to publicize information that could help prevent accidents. Finally, to qualify ''potential hazard'' the way one commenter suggested would not enhance the clarity of the final rule.

The proposal concerning notice of potential hazards is adopted in this final rule as § 192.16(b)(2)—the second item in the list of information to be provided, rather than the last item, as proposed. This rearrangement encourages operators to warn customers of potential hazards at the beginning of notices instead of at the end. A notice may mention just two potential hazards: corrosion and leaks. Most commenters referred to these potential hazards in response to the proposal, and service line accidents generally involve these hazards.

L. Frequency and Time of Notification

1. General

The mandate does not specify how often operators must give their customers maintenance advice or when

they must give them the advice. To clarify these points, we proposed that operators notify existing customers within 6 months after publication of the final rule, and new customers within that time or within 30 days after the service line is placed in service, whichever is later (proposed § 192.16(b)).

2. Number of Notices

Several commenters thought the final rule should clearly state whether operators must notify a customer more than once. Other commenters, including NTSB, felt a single notice to each customer would not be sufficient. They recommended that operators send notices annually (to refresh customer memory), every 2 years, every 5 years, or occasionally.

A single notice sent to each present and future customer would satisfy the mandate. None of the advocates for more frequent notification showed that additional notices would significantly improve safety. Furthermore, the cost of periodic notices would be high, and the effect of customer notification on accident prevention is uncertain. There is also an absence of accumulated accident data on customer piping from which to project the benefits of sending multiple notices to the same customers. Consequently, the final rule expressly states that operators must notify each customer only once.

3. New Customers

Three commenters said the proposed rule was unclear whether ''new customers'' meant new customers on new service lines or new customers on existing service lines. A few operators said it would be a tremendous burden to notify every new customer on an existing service line because of the large changeover in customers. One operator said it has over 100,000 of such new customers annually. These operators would prefer to notify only the first customer on a new service line or to send notices to all customers periodically.

For the mandate to have a continuing effect on customer safety, each present and future customer must receive a maintenance notice if the operator does not maintain covered piping. There would be no continuing effect if operators were to notify just existing customers and the first customers on new service lines. As these customers leave, their successors might lack necessary maintenance information, and the safety of customer piping might decline. So the final rule applies to all new customers. Operators can mitigate the burden of notifying large numbers of customers by inserting general notices in billing envelopes.

To avoid confusion, the final rule does not distinguish new customers from existing customers. Instead, the rule (§ 192.16(c)) requires operators to notify each customer by a certain date, as discussed next.

4. Time of Notification

AGA and several operators recommended a compliance time of 1 year to notify existing customers, instead of 6 months as proposed. They argued that operators would need more time to learn which customers to notify, to draft and send notices, and to instruct personnel to handle inquiries. These commenters also said more time would ease the burden on staff by allowing operators to spread notifications over a longer period.

For new customers, one operator advised that sending notices within 30 days after the customer's service begins would not fit the company's billing cycle. AGA and INGAA suggested an appropriate time to notify new customers would be the time of first billing, rather than when a service line is placed in service.

We proposed a 6-month compliance period to notify existing customers based primarily on our estimate of the time needed to prepare and send out notices. However, in view of the additional information commenters provided, 1 year now seems more appropriate. Further, because service lines are often left in service during customer changeover, the suggestion to notify new customers upon first billing seems reasonable. However, some operators may not choose billing as the method of notification. And, as one commenter remarked, many farm tap customers who receive gas under a right-of-way agreement are not billed. Considering the variations among billing cycles and the alternative means of distributing notices, we believe 90 days after first receipt of gas at a particular location would be a reasonable deadline by which to notify new customers. Therefore, the final rule requires operators to notify each customer not later than 1 year from today or 90 days after the customer first receives gas at a particular location, whichever is later (§ 192.16(c)).

M. Records

The mandate does not require that operators keep records of the advice they give customers. However, as a way to check compliance, we proposed that ''each operator must keep a record of the written notifications'' (proposed § 192.16(c)).

AGA and several operators said the type of record and the retention time were unclear under the proposed rule. Maryland suggested that to see if operators have notified customers, inspectors would have to inspect a record of the date a notice was sent, the name of the customer, and a copy of the notice. In contrast, several operators thought keeping a list of notified customers and the dates they were notified would be too burdensome. Three operators suggested the final rule just require maintenance of a copy of the notice being sent to customers.

To check compliance, RSPA and State inspectors will need to view a copy of the notice operators send customers and evidence that notices have been sent to customers. This evidence may relate to the overall notification process, and need not be customer-specific. For example, a record showing the approximate dates notices are mailed or a written procedure for the notification process would be evidence notices have been sent. More in depth checks on compliance could be conducted where warranted without requiring more detailed records. Therefore, we clarified the final rule to provide that operators must maintain a copy of the notice currently in use and evidence that the notices have been sent to customers as required (§ 192.16(d)). Evidence of notifications more than 3 years old may be discarded.

N. Master Meter Operators

One commenter recommended that we specifically exempt operators of master meter systems from the final rule. Operators of master meter systems purchase gas from pipeline companies through master meters, and then resell and distribute the gas to customers. The customers are usually residents of mobilehome parks or housing projects, the operator's primary enterprise.

In developing the NPRM, we assumed the proposed rules would not affect many master meter operators because they generally own all gas distribution piping up to each customer's dwelling. However, as stated above, WMPA advised that the proposed rules would affect mobilehome parks in California because of customer-owned short sections of connector piping. Although that piping was aboveground and would not come under the final rule, it is reasonable to assume that buried connector piping may occur in some master meter systems. So the proposed rule may have affected small entities to a larger extent than we first pictured.

To mitigate this impact, the final rule (§ 192.16(c)) allows master meter operators to continuously post a general

notice as an alternative to sending notices to customers individually. This type of notification is appropriate for master meter systems because there is commonly a prominent place visited by residents, such as a management office, that is suitable for such posting.

Although the final rule probably does not affect many master meter operators, we did not adopt the suggestion to specifically exempt these operators. As operators of distribution pipelines, they come under the mandate when they do not maintain buried customer piping up to building walls. Also, there is no evidence to suggest that customers of master meter operators have less need for safety information than customers of other operators.

III. Regulatory Analyses and Notices

A. Executive Order 12866 and DOT Policies and Procedures

The Office of Management and Budget (OMB) does not consider this final rule to be a significant regulatory action under section 3(f) of Executive Order 12866. Therefore, OMB did not review the final rule. Also, DOT does not consider the final rule to be significant under its regulatory policies and procedures (44 FR 11034, February 26, 1979). A final regulatory evaluation is available for review in the docket.

B. Executive Order 12612

We analyzed the final rule under the principles and criteria in Executive Order 12612 (''Federalism''). The final rule does not have sufficient federalism impacts to warrant preparation of a federalism assessment.

C. Regulatory Flexibility Act

I certify, under Section 605 of the Regulatory Flexibility Act, that this final rule will not have a significant economic impact on a substantial number of small entities. For purposes of that act, small entities supply gas to fewer than 10,000 customers, and most small entities are operators of master meter systems. As discussed above, most master meter operators do not come under the final rule because they own all gas piping up to building walls. Master meter operators that do come under the rule may comply merely by posting a notice in a prominent location. So compliance cost will be nominal for the bulk of small entities. The remaining small entities, mostly operators of distribution systems in small towns, will be subject to the same rule as other operators. But, as explained above, operators can either avoid notification costs by maintaining covered piping, or mitigate costs by including general notices in billing envelopes.

D. Paperwork Reduction Act

OMB has approved the information collection requirements of this final rule under 44 U.S.C. Chapter 35.

List of Subjects in 49 CFR Part 192

Natural gas, Pipeline safety, Reporting and recordkeeping requirements.

RSPA amends 49 CFR part 192 as follows:

PART 192—[AMENDED]

1. The authority citation for part 192 is revised to read as follows:

Authority: 49 U.S.C. 5103, 60102, 60104, 60108, 60109, 60110, 60113, and 60118; 49 CFR 1.53.

2. Section 192.16 is added to read as follows:

§ 192.16 Customer notification.

(a) This section applies to each operator of a service line who does not maintain the customer's buried piping up to entry of the first building downstream, or, if the customer's buried piping does not enter a building, up to the principal gas utilization equipment or the first fence (or wall) that surrounds that equipment. For the purpose of this section, ''maintain'' means monitor for corrosion according to § 192.465 if the customer's buried piping is metallic, survey for leaks according to § 192.723, and if an unsafe condition is found, either shut off the flow of gas or advise the customer of the need to repair the unsafe condition.

(b) Each operator shall notify each customer once in writing of the following information:

(1) The operator does not maintain the customer's buried piping.

(2) If the customer's buried piping is not maintained, it may be subject to the potential hazards of corrosion and leakage.

(3) Buried gas piping should be—

(i) Periodically inspected for leaks;

(ii) Periodically inspected for corrosion if the piping is metallic; and

(iii) Repaired if any unsafe condition is discovered.

(4) When excavating near buried gas piping, the piping should be located in advance, and the excavation done by hand.

(5) The operator (if applicable), plumbers, and heating contractors can assist in locating, inspecting, and repairing the customer's buried piping.

(c) Each operator shall notify each customer not later than August 14, 1996, or 90 days after the customer first receives gas at a particular location, whichever is later. However, operators of master meter systems may continuously post a general notice in a prominent location frequented by customers.

(d) Each operator must make the following records available for inspection by the Administrator or a State agency participating under 49 U.S.C. 60105 or 60106:

(1) A copy of the notice currently in use; and

(2) Evidence that notices have been sent to customers within the previous 3 years.

Issued in Washington, D.C. on August 9, 1995.

Ana Sol Gutiérrez,

Deputy Administrator.

[FR Doc. 95–20021 Filed 8–11–95; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 640

[Docket No. 950424112–5201–02; I.D. 032095B]

RIN 0648–AF37

Spiny Lobster Fishery of the Gulf of Mexico and South Atlantic; Amendment 4

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to implement Amendment 4 to the Fishery Management Plan for the Spiny Lobster Fishery of the Gulf of Mexico and South Atlantic (FMP). Amendment 4 allows the harvest of spiny lobster year-round and establishes a daily bag or possession limit of two spiny lobster per person in the exclusive economic zone off North Carolina, South Carolina, and Georgia.

EFFECTIVE DATES: September 13, 1995, except for § 640.23(a) and (b) which will be effective [September 21, 1995. The incorporations by reference of certain sections of the Florida Administrative Code and Florida Statutes are approved by the Director of the Office of the Federal Register as of September 13, 1995.

FOR FURTHER INFORMATION CONTACT: Georgia Cranmore, 813–570–5305.

SUPPLEMENTARY INFORMATION: The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils). The FMP is implemented through regulations at 50 CFR part 640 under the authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act).

Detailed descriptions, backgrounds, and rationales for the management measures in Amendment 4 and the additional measures proposed by NMFS were included in the preamble to the proposed rule (60 FR 21493, May 2, 1995) and are not repeated here.

Comments and Responses

Four written comments were received on the proposed rule. One of the Councils' advisory panel members strongly supported this action.

Three recreational divers opposed Amendment 4 because of a perceived risk to lobster stocks from the elimination of the spawning season closure. These three commenters also believe that this action will seriously increase recreational taking of lobsters off North Carolina. Two of the three commenters recommended a monitoring system to determine the number of recreational divers, catch, and size of lobsters before taking this action. One of those commenters opposed to Amendment 4 questioned the data contained in the amendment regarding the depth at which the fishery is prosecuted and the size of available lobsters. This commenter submitted a videotape to the South Atlantic Fishery Management Council office that purports to show lobsters common at depths from 45 to 100 ft (13.7 to 30.5 m) and significant populations of small lobsters in these waters, e.g., carapace lengths less than 1 inch (2.54 cm).

NMFS notes that there is scientific debate regarding the biological status and population dynamics of spiny lobsters in waters north of Florida, including the issue of recruitment and the fate of larvae from the adult population in this area. However, based on the best available scientific information, NMFS and the Councils believe that allowing a limited year-round harvest in the subject area will have no adverse biological impacts on the lobster stocks.

Some divers believe that the spawning season off North Carolina does not begin until July, due to the colder water temperatures. They reported seeing egg-bearing lobsters as late as early October. Thus, the current spawning season closure from April through July, based on data from Florida, may not be particularly relevant to the area north of Florida. Amendment 4 would not change the current prohibition on taking egg-bearing female lobsters.

NMFS believes that a monitoring system for this fishery would not be cost-effective. Our surveys indicate that there are only a small number of participants in the spiny lobster fishery north of Florida. The South Atlantic Council intends to monitor the fishery to determine the need for further management actions, including a possible reduction in the bag limit.

According to testimony at public hearings on Amendment 4, the fishery takes place about 30 nautical miles (55.6 km) offshore in at least 100 ft (30.5 m) of water. A typical dive at these depths lasts less than 30 minutes. Lobsters harvested ranged from 2 to 16 lb (0.9 to 7.3 kg). Comments on the proposed rule contradicted this testimony and raised questions about the potential for significant increases in recreational take and the availability of undersized lobster in the area.

If lobsters are found in relatively shallow water that is accessible to most recreational divers, there is a possibility of an increase in participation due to the year-round harvest. However, a recent NMFS survey indicated that only a small number of recreational divers harvested spiny lobster north of Florida. Comments on the proposed rule also indicate the possible presence of significant numbers of undersized lobsters, i.e., with carapace lengths less than 3 inches (7.62 cm), increasing the possibility of taking undersized lobsters in this fishery. The presence of subadult lobsters was not reported during public hearings on Amendment 4.

NMFS is concerned about the new information that arose during the public comment period on the proposed rule, since this information was not available to the Councils when they approved Amendment 4. However, NMFS has reviewed the administrative record on the Councils' decision and has determined that this new information does not outweigh the record underlying the Councils' decision. Consequently, NMFS approved Amendment 4 with the expectation that the Councils will consider this new information during development of a subsequent FMP amendment.

Incorporation by Reference of Florida Statutes and Regulations

As explained in the proposed rule, NMFS is adding language to the regulatory text of the regulations implementing the FMP to ensure that the incorporations by reference of certain portions of the Florida Statutes (FS) and Florida Administrative Code (FAC) meet procedural specifications of the Office of the Federal Register. NMFS has determined that the references at 50 CFR 640.6(a)(1) to sections 370.14 and 370.142, FS, are unnecessarily broad. The references are in the context of vessel and gear identification requirements applicable to the harvesting of spiny lobsters by traps in Florida's waters. However, such requirements are contained in only three paragraphs of those sections. Accordingly, in this final rule, the references are changed to sections 370.14(2)(a) and (3) and 370.142(2)(b), FS.

The current references are to the portions of the FS and FAC as specified on November 30, 1992. In the proposed rule and this final rule the references are to the FS in effect as of July 1, 1994, and FAC in effect as of June 1, 1994, the dates of the currently effective referenced portions. This change is necessary in order for fishermen to have access to the referenced portions—earlier versions are not readily available. The following changes, none of which are substantive, have been made to the referenced FS and FAC since November 30, 1992:

Section 370.142, FS - paragraph (2)(c) has been removed. The paragraph contained identification requirements for recreational spiny lobster traps. However, those requirements were duplicative of requirements for all traps, as contained in FS 370.14(2)(a) and 370.142(2)(b).

Rule 46–24.002(2), FAC - As of November 30, 1992, this rule specified August 1, 1993, as the beginning date that a restricted species endorsement would be required on the Florida saltwater products license in order to be a commercial harvester of spiny lobsters. That date was changed to August 1, 1994. However, since the reference to this rule was not included in the **Federal Register** until October 21, 1994, the change in date is inconsequential.

In several paragraphs of the referenced FS and FAC ''Department of Natural Resources'' was changed to ''Department of Environmental Protection.''

Changes from the Proposed Rule

As discussed above, the references to sections 370.14 and 370.142, FS, have been changed.

Classification

The Director, Southeast Region, NMFS, determined that Amendment 4 is necessary for the conservation and management of the spiny lobster fishery of the Gulf of Mexico and South

Atlantic and that it is consistent with the Magnuson Act and other applicable law.

This action has been determined to be not significant for purposes of E.O. 12866.

The Assistant General Counsel for Legislation and Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration when the proposed rule was published that it would not have a significant economic impact on a substantial number of small entities. The reasons for this certification were published in the preamble to the proposed rule (60 FR 21493, May 2, 1995). As a result, a regulatory flexibility analysis was not prepared.

The incorporation by reference of certain sections of the Florida Administrative Code and Florida Statutes does not constitute a substantive rule, as they are not changing the regulation, but, rather, are correcting the process by which those sections were previously incorporated. Thus, pursuant to 5 U.S.C. 553(d) there is no need to delay the effective date of those provisions. Additionally, due to the fact that the fishery for spiny lobster opened on August 6, 1995, the Assistant Administrator for Fisheries, NOAA, finds that good cause exists, under 5 U.S.C. 553(d)(3), to waive the 30-day delay in effective date with respect to the provisions of this rule that specify the daily bag or possession limit of spiny lobster. The conservation and management needs that lead NMFS to impose the limit, as described in the proposed rule, along with the fact that it takes little, if any, time to come into compliance with such a limit make a delay in effective date contrary to the public interest and unnecessary, respectively. However, in order to provide time for notice of the bag limit to be provided to fishermen, NMFS will delay the effective date of this provision for 7 days.

List of Subjects in 50 CFR Part 640

Fisheries, Fishing, Incorporation by reference, Reporting and recordkeeping requirements.

Dated: August 9, 1995.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 640 is amended as follows:

PART 640—SPINY LOBSTER FISHERY OF THE GULF OF MEXICO AND SOUTH ATLANTIC

1. The authority citation for part 640 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 640.2, definitions for ''Off the Gulf states, other than Florida'' and ''Off the southern Atlantic states, other than Florida'' are added, in alphabetical order, to read as follows:

§ 640.2 Definitions.

* * * * *

Off the Gulf states, other than Florida means the area from the coast to the outer limit of the EEZ between the Texas/Mexico border to the Alabama/Florida boundary (87°31′06″ W. long.).

Off the southern Atlantic states, other than Florida means the area from the coast to the outer limit of the EEZ between the Virginia/North Carolina boundary (36°34′55″ N. lat.) to the Georgia/Florida boundary (30°42′45.6″ N. lat.).

* * * * *

3. In § 640.4, paragraph (a)(1) is revised to read as follows:

§ 640.4 Permits and fees.

(a) * * *

(1) *Licenses, certificates, and permits*—(i) *EEZ off Florida and spiny lobster landed in Florida.* For a person to sell, trade, or barter, or attempt to sell, trade, or barter, a spiny lobster harvested or possessed in the EEZ off Florida, or harvested in the EEZ other than off Florida and landed from a fishing vessel in Florida, or for a person to be exempt from the daily bag and possession limit specified in § 640.23(b)(1) for such spiny lobster, such person must have the licenses and certificates specified to be a ''commercial harvester,'' as defined in Rule 46–24.002(2), Florida Administrative Code, in effect as of June 1, 1994. This incorporation by reference was approved by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Florida Marine Fisheries Commission, 2540 Executive Center Circle West, Suite 106, Tallahassee, FL 32301; telephone: 904–487–0554. Copies may be inspected at the Office of the Regional Director; the Office of Fisheries Conservation and Management, NMFS, 1315 East-West Highway, Silver Spring, MD; or the Office of the Federal Register, 800 North Capitol Street NW, Suite 700, Washington, DC.

(ii) *EEZ other than off Florida.* For a person to sell, trade, or barter, or attempt to sell, trade, or barter, a spiny lobster harvested in the EEZ other than off Florida or for a person to be exempt from the daily bag and possession limit specified in § 640.23(b)(1) for such spiny lobster, a Federal vessel permit must be issued to the harvesting vessel and must be on board. However, see paragraph (a)(1)(i) of this section for the licenses and certificates required for a person to possess or land spiny lobster harvested in the EEZ other than off Florida and subsequently possessed in the EEZ off Florida or landed from a fishing vessel in Florida.

* * * * *

4. In § 640.6, in paragraph (c), the word ''Secretary'' is revised to read ''Assistant Administrator'' and paragraph (a) is revised to read as follows:

§ 640.6 Vessel and gear identification.

(a) *EEZ off Florida.* (1) An owner or operator of a vessel that is used to harvest spiny lobsters by traps in the EEZ off Florida must comply with the vessel and gear identification requirements applicable to the harvesting of spiny lobsters by traps in Florida's waters in sections 370.14(2)(a) and (3) and 370.142(2)(b), Florida Statutes, in effect as of July 1, 1994, and in Rule 46–24.006(3), (4), and (5), Florida Administrative Code, in effect as of June 1, 1994.

(2) An owner or operator of a vessel that is used to harvest spiny lobsters by diving in the EEZ off Florida must comply with the vessel identification requirements applicable to the harvesting of spiny lobsters by diving in Florida's waters in Rule 46–24.006(6), Florida Administrative Code, in effect as of June 1, 1994.

(3) The incorporation by reference in paragraphs (a)(1) and (a)(2) of this section of sections 370.14(2)(a) and (3) and 370.142(2)(b), Florida Statutes, and Rule 46–24.006(3), (4), (5), and (6), Florida Administrative Code, was approved by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Florida Marine Fisheries Commission, 2540 Executive Center Circle West, Suite 106, Tallahassee, FL 32301; telephone: 904–487–0554. Copies may be inspected at the Office of the Regional Director; the Office of Fisheries Conservation and Management, NMFS, 1315 East-West Highway, Silver Spring, MD; or the Office of the Federal Register, 800 North Capitol Street NW, Suite 700, Washington, DC.

* * * * *

§ 640.7 [Amended]

5. In § 640.7, in paragraph (e), the reference to ''§ 640.20 (c)(1) and (c)(2)'' is revised to read ''§ 640.20(b)(3)(i) and (b)(3)(ii)''; in paragraph (f), the reference to ''§ 640.20(d)'' is revised to read ''§ 640.20(b)(4)''; in paragraph (p), the reference to ''§ 640.23(a) or (b)'' is revised to read ''§ 640.23(a), (b)(1), or (b)(2)'' and the reference to ''§ 640.23(c) and (d)'' is revised to read ''§ 640.23(b)(3) and (b)(4)''; in paragraph (q), the reference to ''§ 640.23(d)'' is revised to read ''§ 640.23(b)(4)''; in paragraph (r), the reference to ''§ 640.23(g)'' is revised to read ''§ 640.23(d)''; and in paragraph (s), the reference to ''§ 640.23(h)'' is revised to read ''§ 640.23(e)''.

6. Section 640.20 is revised to read as follows:

§ 640.20 Seasons.

(a) *EEZ off the southern Atlantic states, other than Florida*. In the EEZ off the southern Atlantic states, other than Florida, there are no seasonal restrictions on the harvest of spiny lobster or on the possession of traps.

(b) *EEZ off Florida and off the Gulf states, other than Florida*—(1) *Commercial and recreational fishing season*. The commercial and recreational fishing season for spiny lobster in the EEZ off Florida and the EEZ off the Gulf states, other than Florida, begins on August 6 and ends on March 31.

(2) *Special recreational fishing seasons*—(i) *EEZ off Florida*. There is a 2-day special recreational fishing season in the EEZ off Florida on the last Wednesday and successive Thursday of July each year during which fishing for spiny lobster is limited to diving or use of a bully net or hoop net. (See § 640.22(a) for general prohibitions on gear and methods.) In the EEZ off Monroe County, Florida, no person may harvest spiny lobster by diving at night, that is, from 1 hour after official sunset to 1 hour before official sunrise, during this 2-day special recreational fishing season.

(ii) *EEZ off the Gulf states, other than Florida*. There is a 2-day special recreational fishing season in the EEZ off the Gulf states, other than Florida, during the last Saturday and successive Sunday of July each year during which fishing for spiny lobster may be conducted by authorized gear and methods other than traps. (See § 640.22(a) for general prohibitions on gear and methods.)

(3) *Possession of traps*. (i) In the EEZ off Florida, the rules and regulations applicable to the possession of spiny lobster traps in Florida's waters in Rule 46–24.005(3), (4), and (5), Florida Administrative Code, in effect as of June 1, 1994, apply in their entirety to the possession of spiny lobster traps in the EEZ off Florida. This incorporation by reference was approved by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Florida Marine Fisheries Commission, 2540 Executive Center Circle West, Suite 106, Tallahassee, FL 32301; telephone: 904–487–0554. Copies may be inspected at the Office of the Regional Director; the Office of Fisheries Conservation and Management, NMFS, 1315 East-West Highway, Silver Spring, MD; or the Office of the Federal Register, 800 North Capitol Street NW, Suite 700, Washington, DC.

(ii) In the EEZ off the Gulf states, other than Florida, a spiny lobster trap may be placed in the water prior to the commercial and recreational fishing season, which is specified in paragraph (b)(1) of this section beginning on August 1 and must be removed from the water after such season not later than April 5.

(iii) A spiny lobster trap, buoy, or rope in the EEZ off Florida or in the EEZ off the Gulf states, other than Florida, during periods not authorized in paragraphs (b)(3)(i) and (b)(3)(ii) of this section will be considered unclaimed or abandoned property and may be disposed of in any manner considered appropriate by the Assistant Administrator or an authorized officer. An owner of such trap, buoy, or rope remains subject to appropriate civil penalties.

(4) *Possession of spiny lobsters*. In the EEZ off Florida and the Gulf states, a whole or a part of a spiny lobster subject to these regulations may only be possessed during the commercial and recreational fishing season and the special recreational fishing season specified in § 640.20, unless accompanied by proof of lawful harvest in the waters of a foreign nation. Consistent with the provisions of paragraphs (b)(3)(i) and (ii) of this section, a spiny lobster in a trap in this area will not be deemed to be possessed provided such spiny lobster is returned immediately to the water unharmed when a trap is removed from the water between March 31 and April 15.

(c) *Primacy of seasonal restrictions in the EEZ off Florida*. The seasonal restrictions applicable in the EEZ off Florida apply to all spiny lobsters and traps in the EEZ off Florida, without regard to harvest or use elsewhere, unless accompanied by proof of lawful harvest elsewhere.

7. In § 640.22, a sentence is added to the end of paragraph (a)(1) and paragraph (b)(3)(i) is revised to read as follows:

§ 640.22 Gear and diving restrictions.

(a) * * *

(1) * * * Hook, as used in this paragraph (a)(1), does not include a hook in a hook-and-line fishery for species other than spiny lobster; and possession of a spiny lobster that has been speared, pierced, or punctured by such hook is not considered evidence that prohibited gear was used to take the spiny lobster, provided no prohibited gear is on board the vessel.

* * * * *

(b) * * *

(3) * * *

(i) For traps in the EEZ off Florida, by the Florida Division of Law Enforcement, Department of Environmental Protection, in accordance with the procedures in Rule 46-24.006(7), Florida Administrative Code, in effect as of June 1, 1994. This incorporation by reference was approved by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Florida Marine Fisheries Commission, 2540 Executive Center Circle West, Suite 106, Tallahassee, FL 32301; telephone: 904–487–0554. Copies may be inspected at the Office of the Regional Director; the Office of Fisheries Conservation and Management, NMFS, 1315 East-West Highway, Silver Spring, MD; or the Office of the Federal Register, 800 North Capitol Street NW, Suite 700, Washington, DC.

* * * * *

8. Section 640.23 is revised to read as follows:

§ 640.23 Bag/possession limits.

(a) *EEZ off the southern Atlantic states, other than Florida*. The daily bag or possession limit for spiny lobster in or from the EEZ off the southern Atlantic states, other than Florida, is two per person for commercial and recreational fishing, year-round.

(b) *EEZ off Florida and off the Gulf states, other than Florida*—(1) *Commercial and recreational fishing season*. Except as specified in paragraphs (b)(3) and (b)(4) of this section, during the commercial and recreational fishing season specified in § 640.20(b)(1), the daily bag or possession limit of spiny lobster in or from the EEZ off Florida and off the Gulf states, other than Florida, is six per person.

(2) *Special recreational fishing seasons*. During the special recreational

fishing seasons specified in § 640.20(b)(2), the daily bag or possession limit of spiny lobster—

(i) In or from the EEZ off the Gulf states, other than Florida, is six per person;

(ii) In or from the EEZ off Florida other than off Monroe County, Florida, is twelve per person; and

(iii) In or from the EEZ off Monroe County, Florida, is six per person.

(3) *Exemption from the bag/possession limit.* During the commercial and recreational fishing season specified in § 640.20(b)(1), a person is exempt from the bag and possession limit specified in paragraph (a) of this section, provided—

(i) The harvest of spiny lobsters is by diving, or by the use of a bully net, hoop net, or spiny lobster trap; and

(ii) The vessel from which the person is operating has on board the required licenses, certificates, or permits, as specified in § 640.4(a)(1).

(4) *Harvest by net or trawl.* During the commercial and recreational fishing season specified in § 640.20(b)(1), aboard a vessel with the required licenses, certificates, or permits specified in § 640.4(a)(1) that harvests spiny lobster by net or trawl or has on board a net or trawl, the possession of spiny lobster in or from the EEZ off Florida and off the Gulf states, other than Florida, may not exceed at any time 5 percent, whole weight, of the total whole weight of all fish lawfully in possession on board such vessel. If such vessel lawfully possesses a separated spiny lobster tail, the possession of spiny lobster in or from the EEZ may not exceed at any time 1.6 percent, by weight of the spiny lobster or parts thereof, of the total whole weight of all fish lawfully in possession on board such vessel. For the purposes of this paragraph (b)(4), the term ''net or trawl'' does not include a hand-held net, a loading or dip net, a bully net, or a hoop net.

(5) *Diving at night.* The provisions of paragraph (b)(3) of this section notwithstanding, a person who harvests spiny lobster in the EEZ by diving at night, that is, from 1 hour after official sunset to 1 hour before official sunrise, is limited to the bag limit specified in paragraph (b)(1) of this section, whether or not a Federal vessel permit specified in § 640.4(a)(1) has been issued to and is on board the vessel from which the diver is operating.

(c) *Combination of bag/possession limits.* A person who fishes for or possesses spiny lobster in or from the EEZ under a bag or possession limit specified in paragraph (a) or (b) of this section may not combine the bag or possession limits of those paragraphs or combine such bag or possession limit with a bag or possession limit applicable to state waters.

(d) *Responsibility for bag/possession limits.* The operator of a vessel that fishes for or possesses spiny lobster in or from the EEZ is responsible for the cumulative bag or possession limit specified in paragraphs (a) and (b) of this section applicable to that vessel, based on the number of persons aboard.

(e) *Transfer at sea.* A person who fishes for or possesses spiny lobster in or from the EEZ under a bag or possession limit specified in paragraph (a) or (b) of this section may not transfer a spiny lobster at sea from a fishing vessel to any other vessel, and no person may receive at sea such spiny lobster.

§ 640.24 [Amended]

9. In § 640.24, the word ''Secretary'' is revised to read ''Assistant Administrator''.

[FR Doc. 95–20024 Filed 8–11–95; 8:45 am]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 60, No. 156
Monday, August 14, 1995

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 Parts 1030, 1065, 1068, 1076 and 1079

[Docket Nos. AO–361–A31, etc.; DA–92–27]

Milk in the Chicago Regional and Other Marketing Areas; Decision on Proposed Amendments to Marketing Agreements and to Orders

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

7 CFR Part	Marketing area	AO Nos.
1030 ..	Chicago Regional	AO–361–A31
1065 ..	Nebraska-Western Iowa.	AO–86–A50
1068 ..	Upper Midwest	AO–178–A48
1076 ..	Eastern South Dakota.	AO–260–A32
1079 ..	Iowa	AO–295–A44

SUMMARY: This final decision adopts changes in the Federal milk marketing orders for five north central marketing areas based on industry proposals considered at a public hearing. The decision adopts a plan for pricing milk on the basis of its protein and other nonfat solids, as well as butterfat, components. The proposed plan includes adjustments per hundredweight based on the somatic cell count of producer milk used in Class II and Class III, and on payments to producers of all pooled milk.

FOR FURTHER INFORMATION CONTACT: Constance M. Brenner, Marketing Specialist, USDA/AMS/Dairy Division, Order Formulation Branch, Room 2968, South Building, P.O. Box 96456, Washington, DC 20090–6456, (202) 720–2357.

SUPPLEMENTARY INFORMATION: This administrative action is governed by the provisions of sections 556 and 557 of Title 5 of the United States Code and therefore is excluded from the requirements of Executive Order 12866.

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires the Agency to examine the impact of a proposed rule on small entities. Pursuant to 5 U.S.C. 605(b), the Administrator of the Agricultural Marketing Service has certified that this rule will not have a significant economic impact on a substantial number of small entities. The amended orders will promote more orderly marketing of milk by producers and regulated handlers.

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

The Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), 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 the law and requesting a modification of an order or to be exempted from the order. A handler is afforded the opportunity for a hearing on the petition. After a hearing, the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has its principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after the date of the entry of the ruling.

Prior documents in this proceeding;

Notice of Hearing: Issued December 22, 1993; published January 4, 1994 (59 FR 260).

Extension of Time for Filing Briefs: Issued April 22, 1994; published April 29, 1994 (59 FR 22138).

Recommended Decision: Issued October 25, 1994; published November 2, 1994 (59 FR 54952).

Extension of Time for Filing Exceptions: December 2, 1994; published December 9, 1994 (59 FR 63733).

Preliminary Statement

A public hearing was held upon proposed amendments to the marketing agreements and the orders regulating the handling of milk in the Chicago Regional and certain other marketing areas. The hearing was held, pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and the applicable rules of practice (7 CFR Part 900), at Bloomington, Minnesota, on January 25–27, 1994. Notice of such hearing was issued on December 22, 1993, and published January 4, 1994 (59 FR 260).

Upon the basis of the evidence introduced at the hearing and the record thereof, the Administrator, on October 25, 1994, issued a recommended decision containing notice of the opportunity to file written exceptions thereto.

The material issues, findings and conclusions, rulings, and general findings of the recommended decision are hereby approved and adopted and are set forth in full herein, subject to the following modifications:

1. Under Issue 1, the last sentence in paragraph 1 is revised, the second sentence in paragraph 23 is revised, a paragraph is added after paragraph 34, and two paragraphs are added after paragraph 40.

2. Two paragraphs are added at the end of Issue 2.

3. Under Issue 3, one paragraph is added after paragraph 5, the first sentence of paragraph 8 is revised, and a paragraph is added at the end of Issue 3.

4. Under Issue 3a, a phrase is modified in paragraph 5, four paragraphs are added after paragraph 25, and two paragraphs are added at the end of Issue 3a.

5. Under Issue 3b, paragraph 1 is modified, one paragraph is added after paragraph 7, one paragraph is added after paragraph 8, and one paragraph is added at the end of Issue 3b.

6. Under Issue 3c, a sentence is added at the end of paragraph 3.

7. Under Issue 4, paragraph 1 is modified, paragraph 26 is modified and expanded into three paragraphs, the last four sentences of paragraph 34 and all of paragraphs 35 and 36 are deleted, and 34 paragraphs are added at the end of Issue 4.

8. Under Issue 5, paragraphs 1 and 4 are revised, paragraph 5 is replaced by two new paragraphs, two paragraphs are added after paragraph 12, paragraph 16 is revised, and two paragraphs are added at the end of Issue 5.

The material issues on the record of the hearing relate to:

1. Adoption of multiple component pricing.
2. Orders to be included.
3. Components and component prices.
a. Protein.
b. Other nonfat solids.
c. Butterfat.
d. Miscellaneous issues.
4. Somatic cell adjustment.
5. Conforming changes.

Findings and Conclusions

The following findings and conclusions on the material issues are based on evidence presented at the hearing and the record thereof:

1. *Adoption of multiple component pricing.* Proposals to incorporate multiple component pricing in the Chicago Regional (Order 30), Nebraska-Western Iowa (Order 65), Upper Midwest (Order 68), Eastern South Dakota (Order 76) and Iowa (Order 79) Federal milk marketing orders (the five orders) should be adopted, with some modifications. The pricing plan generally would be patterned after the multiple component pricing plan proposed by National All-Jersey, Inc. and other dairy organizations. Producers would be paid on the basis of the pounds of butterfat, protein and other nonfat solids (solids-not-fat other than protein) in their milk, and would share in the value of the pool's Class I and Class II uses on a per hundredweight basis. Regulated handlers would pay for the milk they receive on the basis of total butterfat, the protein and other nonfat solids used in Classes II and III, skim milk used in Class I, and the hundredweight of total product used in Classes I and II. In a modification from the recommended decision, a somatic cell adjustment, per hundredweight, would apply to the value of milk used in Classes II and III, but not in Class I, and to the value of all producer milk. The change was necessary since the record evidence as discussed later did not support including Class I.

At the present time, milk received by handlers under the five orders is priced according to the pounds of producer milk allocated to each class of use multiplied by the prices per hundredweight of milk testing 3.5 percent butterfat, as determined under the orders for each class of use. Adjustments for such items as overage, reclassified inventory, location and other source milk allocated to Class I are added to or subtracted from the classified use value of the milk. The resulting amount is divided by the total producer milk in the pool to calculate a price per hundredweight of milk testing 3.5 percent butterfat to be paid to producers for the milk they have delivered to handlers. The price paid to each producer is then adjusted according to the specific butterfat test of the producer's milk by means of a butterfat differential. The butterfat differential is computed by multiplying the wholesale selling price of Grade A (92-score) bulk butter per pound on the Chicago Mercantile Exchange, as reported for the month by the U.S. Department of Agriculture, by 0.138 and subtracting the Minnesota-Wisconsin price (the M–W price) at test, also as reported by the U.S. Department of Agriculture, multiplied by .0028.

The multiple component pricing (MCP) plan was originally proposed for Orders 30, 68 and 79 by National All-Jersey, Inc. (NAJ), and other dairy organizations. In addition, Land O'Lakes, Inc., proposed that the multiple component plan be considered for Orders 65 and 76. Most other proposals considered at the hearing were modifications of the NAJ proposal and are discussed below.

The first NAJ witness stated that the current milk pricing system used in the five orders does not meet current marketing needs and should be replaced with a multiple component pricing system. Much of the general NAJ testimony in favor of multiple component pricing was later reiterated by witnesses expert in the field of economics and dairy chemistry testifying for NAJ, and a representative for Land O'Lakes. Also testifying in favor of the NAJ proposal were two dairy farmer members of the cooperative association Swiss Valley Farms Company, a representative of the Brown Swiss Cattle Breeders Association of U.S.A., Inc., and a representative of Tri-State Milk Cooperative. It was indicated in testimony that Alto Dairy Cooperative also supported the NAJ proposal.

The representative for the proponents said the intent of their proposal was to:

1. Use the M–W price as the base;
2. Pay all producers on four factors—pounds of butterfat, pounds of protein, pounds of other solids, and each producer's share of the fluid differential on a per hundredweight basis;
3. Leave Class I handler obligations on a skim-butterfat basis;
4. Determine Class II and III handlers' obligations on the basis of pounds of butterfat, protein, and other solids; and
5. Change only the order provisions needed to implement the NAJ proposal.

The NAJ witness said that there were five reasons for replacing the current milk pricing system with a multiple component pricing system. The first reason, according to the NAJ witness, is that the current skim-butterfat pricing system does not give dairy farmers economic incentives to produce milk high in nonfat solids, especially protein. He stated that under the current pricing system a pound of water receives the same price as a pound of protein or other solids, yet it is these solids that give milk its functional and nutritional value.

The second reason given by the NAJ witness for adopting MCP was that over a period of years much of the value of milk has shifted from butterfat to the skim portion of milk. The proponent's witness said that in 1960, butterfat represented 77% of the value of the M–W price, and skim represented 23%. By 1993, he testified, these values were reversed, with butterfat representing only 23% of the value of the M–W, while the skim portion of the milk represented 77%.

According to the NAJ witness, the shift in value from butterfat to skim was partially caused by the USDA decision to decrease the support price for butter and increase the support price for nonfat dry milk. The support price for butter declined from $1.53 per pound in 1981 to 65¢ per pound in 1993, with most of the decrease occurring since 1989. Nonfat dry milk purchase prices under the support program increased from 72.75¢ per pound in 1988 to $1.034 per pound in 1993. In addition, the witness said, the butterfat differential under Federal orders has been dropping since the mid-1980s because of a decline in the market price for butter. This drop was accelerated by a change in the method of computing the butterfat differential, implemented in 1990, that had the impact of reducing the butterfat differential even more.

The third reason the witness gave for implementing multiple component pricing was the shift in types of dairy products consumers are purchasing. According to the witness, some of the decline in butterfat value relative to skim value has been caused by a shift in consumption from whole milk to lowfat and skim fluid milk products. The witness presented data to show that from 1970 to 1991, national fluid milk sales of lowfat and skim milk increased 232%, while sales of whole milk declined 50%. In addition, he stated, consumption of lowfat manufactured products is growing faster than

consumption of relatively high-fat manufactured products.

The NAJ witness discussed equity in Federal orders as the fourth reason for implementing multiple component pricing. He said that the current skim-butterfat pricing system is equitable for neither producers nor handlers since it does not properly recognize the value of protein, especially in manufactured products such as cheese. The witness provided examples to show how a producer with high protein milk may currently receive the same Federal order minimum price as a producer with low protein milk. Similarly, a cheese maker who purchases high protein milk could have a cost advantage at minimum order prices over a cheese maker who purchases low protein milk.

The fifth reason presented by the NAJ witness was the existence of a number of voluntary multiple component pricing plans in the areas covered by the five orders. Data were presented to show that nearly all producers in the five orders currently are eligible to be paid under one of these voluntary multiple component pricing plans. The witness stated that many of the plans have inadequacies which contribute to disorderly marketing. According to the witness, these inadequacies would be addressed by adopting the NAJ proposal.

A witness from Land O'Lakes, Inc. (LOL), testified in support of the adoption of MCP in the five orders in general, and the NAJ proposal specifically. He discussed how the NAJ multiple component pricing proposal would better reflect the market value of nutrients in the milk to the farmer. He stated that the proposed system, compared with the current system, would essentially eliminate the value of milk used in manufacturing that is currently associated with water which, he said, has very little market value in dairy products. The witness said that MCP would affect the cost of milk to LOL as a handler in that it will come closer to equalizing the cost of milk relative to the value of the products derived from the milk.

The LOL witness also described four major weaknesses in the existing voluntary MCP plans. The first weakness, he said, was that the current plans emphasize component test instead of component yield. He said that the price paid to each producer should be tied more directly to the value of the products that can be produced from the producer's milk.

The second weakness described by the LOL witness is that many existing plans do not provide for deductions for milk with low component levels. This, he said, indicates that the plans recognize the higher value of milk with more pounds of components, but do not recognize that milk with fewer pounds of components is worth less. He said that competitive, rather than economic, factors are the reason deductions for low component levels generally do not exist, as many producers do not like to see deductions on their milk checks.

According to the LOL witness, an inequitable feature of the voluntary MCP plans is that they generally pay no component premiums when the somatic cell count of the milk is above a fixed level, resulting in high test producers losing their component premium because of high somatic cells, while low test producers with high somatic cell counts lose nothing.

The fourth weakness described by the witness is that some existing MCP plans pay premiums for protein, while others pay premiums for solids-not-fat. He said that most producers in Wisconsin receive premiums based on protein, while most producers in Minnesota, Iowa, Nebraska and South Dakota receive premiums based on solids-not-fat. The witness claimed that the variety of payment plans currently in existence do a poor job of transmitting market signals to the producers, are not economically consistent, and lead to confusion among farmers. He said that the NAJ proposal would address the deficiencies in the current situation.

Most participants at the hearing advocated the introduction of MCP for payments to producers and for milk delivered to handlers for Class II and Class III use in the five orders. There was no support for pricing Class I milk on other than the current butterfat and skim basis.

In addition to NAJ and LOL, adoption of some form of multiple component pricing in the five orders was supported by Central Milk Producers Cooperative (CMPC), the Trade Association of Proprietary Plants (TAPP), Farmers Union Milk Marketing Cooperative (FUMMC), National Farmers Organization (NFO), Kraft General Foods (Kraft), Associated Milk Producers, Inc., North Central Region (AMPI-North Central), Wisconsin Cheese Makers Association (WCMA), Dean Foods, and National Cheese Institute (NCI).

The CMPC witnesses strongly supported the need for implementing multiple component pricing in the five orders and proposed a plan very similar to that of NAJ. The fundamental difference between the two plans is that the CMPC proposal would result in lower protein prices than the NAJ proposal. The appropriate level of the protein price is discussed under Issue 3a below.

The CMPC proposal was supported in testimony and in a post-hearing brief by NFO. A witness for WCMA testified in support of the CMPC proposal for multiple component pricing. A witness for Dean Foods testified in support of the concept of MCP, and in response to a question about which proposal he favored, he expressed support for the CMPC proposal. AMPI North Central Region submitted a brief in support of the CMPC proposal for multiple component pricing.

A witness for NCI testified in support of the CMPC multiple component pricing proposal with one primary modification. The NCI proposal would calculate a ''residual fluid price'' instead of another solids price. This proposal is discussed further under Issue 3b below in this decision. Kraft testified and submitted a brief in support of the NCI proposal for multiple component pricing.

A witness for the Trade Association of Proprietary Plants (TAPP) and Farmers Union Milk Marketing Cooperative (FUMMC) testified in support of the TAPP proposal, a variation of the CMPC proposal that would price both butterfat and protein on a differential basis, rather than on a per-pound basis.

The five north central Federal milk orders included in this proceeding should be amended to include multiple component pricing. On the basis of the record of this proceeding, multiple component pricing would entail pricing milk on the basis of the pounds of butterfat, protein and other nonfat solids contained in the milk, with a somatic cell adjustment to the hundredweight of milk used in Classes II and III and to the producer price differential paid to producers. The record indicates that a large percentage of the producers pooled under these orders are already eligible for or receive some form of multiple component pricing and that many of these component pricing plans use protein as a pricing component.

The record also shows that the diverse component pricing programs that currently exist promote disorderly and inefficient marketing conditions in the procurement of milk supplies by competing handlers. The different programs establish non-uniform bases of payments to producers. The adoption of multiple component pricing will allow the Orders to recognize the additional value of milk with a higher-than-average solids content.

In the five orders included in this proceeding, the vast majority of the milk pooled is utilized in manufactured products. The total solids in the milk

used for manufacturing are the primary determinants of product yield. In addition, it is the solids in fluid milk that give it its nutritional value and taste. In both types of products, the current pricing system used in the five orders does not properly recognize the value of nonfat milk solids or encourage producers to increase the quantity of nonfat milk solids in the milk they produce.

As a result of the shift in value in recent years from the butterfat portion of milk to the skim portion, most of the value of milk is determined on a volume basis without any consideration of the value of the skim components. Adoption of the multiple component pricing plan recommended in this decision will enable the market to reflect the value of the skim components in milk to producers.

In addition to butterfat, protein is clearly the most appropriate component of milk on which payment should be based. Most of the milk pooled under these five orders is used for manufacturing, and 86% of the milk used in manufacturing is used to produce cheese. Because protein is a main determinant of cheese yield, and it is cheese that determines the profitability for most of the dairy industry in the 5-market area, the milk pricing system should recognize the value of the protein component of milk as it is used in the manufacture of cheese.

Record evidence clearly shows that protein has a higher demand than other components of milk because of its functional, nutritional and economic value in the marketplace. The functional characteristics of protein allow it to form the matrix in the production of cheese and yogurt. Protein is also important to the air formation in the manufacture of certain products and provides some required nutrients in the human diet. Milk containing a higher percentage of protein will result in greater yields of most manufactured products than milk with a lower protein test. Additionally, handlers receiving milk that results in greater volumes of finished products such as cheese and cottage cheese than an equivalent volume of milk testing lower in protein should be required to pay more for the higher-testing milk. At the same time, the dairy farmer producing milk that yields greater amounts of finished products deserves to be paid more for it than a dairy farmer producing the same volume of milk that results in less product yield. Thus, sending an economic signal to dairy farmers will encourage them to maximize the production of those components which have the greatest demand in the marketplace.

According to analysis of the record, proponents are correct that attribution of all of the skim value of the M-W price to protein would result in an overstatement of the value of protein used in cheese and most other uses. In order to maintain fairly uniform prices between orders for milk used in manufactured products, it is necessary to assign the residual value of the M-W price minus the butterfat and protein values to either other nonfat solids or a fluid carrier price. The discussion of this residual component may be found in Issue 3b below.

A witness for the Galloway Company testified in support of TAPP and Galloway's own proposals to exclude sweetened condensed milk, ice cream and ice cream mix from pricing under a multiple component pricing system. The witness stated that such products should continue to be priced under the current pricing system.

The Galloway witness said that some Class II manufactured products, together with other products such as sour cream, whipping cream, half and half, eggnog, yogurt, nonfat dry milk and butter, are not affected in yield by the protein content of the milk from which the products are manufactured. Instead, according to the witness, it is total skim solids that affect the yield of these products. Accordingly, the witness stated, it would not be equitable to price such products under a multiple component pricing system which prices protein at a level higher than the remaining skim solids in the milk. The witness argued that these products should be left out of any MCP plan adopted.

The Galloway witness testified, and post-hearing briefs filed on behalf of Anderson-Erickson (A-E) and Galloway asserted, that yields are affected by the level of total skim solids rather than protein, making the pricing of protein irrelevant for Class II pricing. The Galloway witness testified that there have been months in which the monthly average protein level and other nonfat solids level of milk moved in opposite directions. In addition, the A-E and Galloway briefs asserted that MCP would significantly increase the cost of Class II milk, which would put them at an even greater disadvantage than currently with respect to products made from nonfat dry milk priced at the Class III-A price.

The Galloway witness stated that the primary product manufactured by the Galloway Company is sweetened condensed milk. According to the witness, this product competes on a national basis with other manufacturers who do not have to procure their milk under Federal orders with MCP provisions. The witness stated that it would be unfair to force his organization to procure milk under a set of regulations that differ from those regulating his competitors.

A portion of the TAPP proposal would require a classification change for sweetened condensed milk from Class II to Class III. Although the Galloway witness expressed strong concern over the impact of multiple component pricing on his company, the effect of the classification of sweetened condensed milk on the Galloway company is not part of the MCP issue. Reclassification of this product is a separate issue that was discussed thoroughly at a previous hearing, and in the decision issued as a result of that hearing (58 FR 27774). No new evidence was presented at this hearing that would justify reclassifying sweetened condensed milk.

Comments filed in response to the recommended decision on behalf of A-E excepted to the application of component pricing to certain Class II products. A-E's opposition was based on two points: (1) The value of the protein in certain Class II products cannot be recovered in the marketplace, and (2) there was no evidence at the hearing to justify an increase in the Class II price. Dean Foods' comments expressed concern that MCP might jeopardize Class II product standing in the marketplace, but didn't oppose or support inclusion of MCP for Class II.

Milk used to produce sweetened condensed milk, or any other Class II product, should not be exempted from multiple component pricing. The MCP plan recommended for adoption will cover all Class II and Class III products.

Testimony at the hearing indicated that there are essentially two groups of Class II products that differ with respect to the impact of multiple component pricing on the handlers that make these products. The first group of Class II products are those in which there generally seemed to be agreement in the hearing record that yields are greatly affected by the level of protein in the milk. These products include the various cottage cheeses and other similar soft, high-moisture cheeses. The handlers that make these products benefit directly from higher levels of protein in milk and should be accountable to the pool for this added benefit.

The second group of Class II products are those where there was some disagreement in the record about the effect of protein on the yield. These products include ice cream and frozen

desserts and mixes, fluid creams, sour creams, yogurt, sweetened condensed milk and others. Considerable debate took place on whether it was appropriate to include these products in a multiple component pricing system.

Occurrences of average protein level and other nonfat solids level of milk moving in opposite directions appear to be exceptions rather than the rule. Evidence presented in ''Analysis of Component Levels and Somatic Cell Counts in Individual Herd Milk at the Farm Level, 1992, Upper Midwest Marketing Area'' indicates that about 60% of the variation in solids-not-fat is caused by variation in protein, and that higher protein levels are positively correlated with higher solids-not-fat levels. Data presented in this and other documents show that the level of other solids in milk tends to be relatively constant with, generally, small month-to-month variation. Thus, when a handler purchases milk with higher than average protein levels, he will also, generally, be purchasing milk with higher than average levels of solids-not-fat.

In addition, the sum of the value of the protein and other solids under this recommended pricing plan equals the value of the total nonfat solids. The value of total nonfat solids, therefore, is a weighted average of the quantity and price of the protein and the quantity and price of the other nonfat solids contained in the milk. Analysis based on the average tests of the five markets shows that under the recommended pricing plan, the value of total nonfat solids would range from approximately $.002 per pound below the current value to approximately $.008 per pound above the current value.

This estimated price difference is certainly not the significant increase that is claimed in the briefs. In hearing testimony, the Galloway witness stated that an analysis of the effect of the CMPC proposal on the Galloway Company showed a nine-cent increase per hundredweight in the cost of Galloway's milk only when the CMPC somatic cell adjustment was included. Without the somatic cell adjustment, the analysis showed that the cost of milk to Galloway would be reduced under the CMPC multiple component pricing plan.

As explained above, protein is not the only component in skim milk. Skim milk consists of protein and other solids which are combined in this pricing plan to determine the value of skim milk. As was described earlier, the total value of the nonfat solids under MCP ranges from approximately $.002 per pound below to $.008 per pound above the current value of nonfat solids in the skim portion of milk.

Contrary to claims in the A–E exception, the Class II price does not change under the MCP pricing plan. The value of milk used in Class II may change, depending on the level of solids contained in the milk. However, the MCP value could be lower or higher than the current skim value, not just higher as assumed by A–E.

It is appropriate to include all Class II products in the multiple component pricing system being proposed here. All Class II products derive benefit from butterfat, protein and/or other solids in the milk. The benefit may be in enhanced yield, such as protein for cottage cheese, or a combination of protein and other solids (i.e. the solids-not-fat in the milk) in many of the other Class II products. Or, the benefit may be in some other area. For example, the NAJ dairy chemist witness testified about the importance of protein in the functionality of many of these products, such as in ice cream, whipping cream, and yogurt. Some testimony even went so far as to discuss the importance of protein in fluid milk, in terms of the nutrient content and the mineral carrying content of the milk. However, since there was no substantial support for including Class I milk in the multiple component pricing system being proposed here, only Class II and Class III products will be priced on multiple components.

2. *Orders to be included.* A proposal to incorporate the multiple component pricing plan adopted in this proceeding in the Nebraska-Western Iowa and Eastern South Dakota Federal milk orders as well as in the Chicago Regional, Iowa, and Upper Midwest orders should be adopted.

The witness for Land O'Lakes (LOL), proponent of the proposal, listed a number of reasons for including the multiple component pricing plan in the Nebraska-Western Iowa and Eastern South Dakota orders as well as in the orders proposed by NAJ. The witness explained that all five orders are similar in that their predominant use of milk is for manufacturing Class III products. He testified that the primary organizations that supply the Nebraska-Western Iowa and Eastern South Dakota markets also are major participants in one or more of the Chicago Regional, Iowa, and Upper Midwest order marketing areas. The witness stated that inclusion of the Nebraska-Western Iowa and Eastern South Dakota orders in the multiple component pricing plan would allow those organizations that have producers and market milk in multiple orders to standardize their payrolls and billings, thus maintaining uniformity and reducing confusion among producers and handlers.

The decision to include additional orders in this decision should not be made entirely on the basis of convenience to the parties marketing milk on the various orders. The decision is based on whether inclusion of the two orders would tend to effectuate the policy of the Agricultural Marketing Agreement Act. Certainly, including the Nebraska-Western Iowa and Eastern South Dakota orders in this decision will contribute to orderly marketing.

The data supplied by the market administrators' offices describing the milksheds of the various orders shows a considerable overlap of milksheds. For example, many South Dakota counties have milk pooled on three of the five orders during the same month. In the absence of uniform pricing provisions between the five orders, disorderly marketing could occur, particularly when orders have overlapping milksheds, if one order were pricing milk on a skim and butterfat basis while another order was pricing milk on the basis of its components. If a producer's milk tests high for nonfat components but is pooled under an order that prices milk on a skim-butterfat basis, the producer would attempt to maximize returns by changing the market under which his milk is pooled to benefit from his high component levels. The opposite situation would occur if the milk of a producer testing below average for nonfat components is pooled under an order with MCP provisions. Such a producer would maximize returns by changing the order under which his milk is pooled to one with skim-butterfat pricing. This shuffling of producers in the same geographic area because of nonuniform pricing provisions would not constitute orderly marketing.

Since the inclusion of the Nebraska-Western Iowa and Eastern South Dakota orders in the multiple component pricing decision would tend to reduce disorderly marketing in the region, benefit handlers by allowing a standardized payroll, and there was no opposition to their inclusion, multiple component pricing should be adopted for these two orders as well as the other three.

In response to the recommended decision, NCI and TAPP filed comments advocating a uniform national MCP plan. NCI stated that a uniform MCP plan should be considered for all markets with a significant quantity of manufacturing milk and production of a significant quantity of cheese. TAPP's comments argued that emphasizing the

value of protein in cheese is inappropriate if a national uniform multiple component pricing plan is contemplated.

The multiple component pricing plans considered thus far for inclusion in Federal milk orders have been developed and proposed by the industry participants in the affected marketing areas. The plans have tended to be modified from one proceeding to the next, with ideas about the most appropriate provisions evolving as time goes on, and to reflect individual marketing conditions. The evidence in the record of this proceeding supports the pricing plan adopted in this decision for these 5 markets. Implementation of a multiple component pricing plan for these 5 markets should not be delayed because of the desire of some market participants for a national plan.

3. *Components and component prices*. Unlike the multiple component pricing plans adopted previously in other Federal milk marketing orders, this decision recommends the adoption of a pricing plan for milk based on three components rather than two. Under the five orders involved in this decision, milk should be priced on the basis of its protein, other nonfat solids, and butterfat components.

The protein price contained in this decision is based on the value of protein in the manufacture of cheese, as determined by cheese market prices, and is not a residual of the Minnesota-Wisconsin (M–W) price minus butterfat value as is the case in other MCP plans. The butterfat price would be based on the butter market, as it is in other multiple component pricing systems. ''Other nonfat solids'' will be priced as a residual of the M–W price minus protein value and butterfat value. The butterfat, protein, and other nonfat solids prices shall be expressed in dollars per pound carried to the fourth decimal place. In addition, payments to each producer should reflect the value of participation in the marketwide pools on a hundredweight basis.

As in other orders for which multiple component pricing has been adopted, this decision maintains the relationship of the value of producer milk to the M–W price. If the sum of the butterfat value and the protein value is greater than the M–W price, a situation which would result in a negative other nonfat solids price, the protein price will be adjusted such that the other nonfat solids price will be zero.

In testimony and brief a witness for the Trade Association of Proprietary Plants (TAPP) and Farmers Union Milk Marketing Cooperative (FUMMC) presented a plan that would pay producers for protein above a neutral zone of 3.00% to 3.29%, and provide deductions for protein levels below the neutral zone. The level of adjustment would be tied to the price of barrel cheddar cheese on the National Cheese Exchange, and would be used to adjust pay prices to producers in a manner similar to the current butterfat differential.

The witness said that milk traditionally has been purchased on a per hundredweight basis, with differential adjustments for levels of components. According to the witness, not only are producers usually paid on a per hundredweight basis, but milk is measured on a per hundredweight basis for purposes of plant accounting, payments between plants and to haulers, and by breed associations and DHIA with adjustments for percentages of components where necessary. The witness also claimed that using differential pricing would be revenue neutral.

Comments filed by TAPP in response to the recommended decision argued that the recommended pricing provisions would result in excessive price deviations between current and projected producer returns, and that a wide neutral zone of no adjustments for protein content should be included. TAPP's comments, and those of the North Dakota Milk Producers Association, reiterated the arguments for continuing to price milk on a hundredweight basis, with differentials for adjusting its value for protein and butterfat content. TAPP further predicted that pricing components on a per-pound basis would lead to discontinued use of the M–W price, as handlers of Grade B milk also would shift their payments to producers to a component basis.

The TAPP/FUMMC testimony and comments are correct that switching payments to producers from a per hundredweight system to one of pounds of components, as adopted in this decision, is not a minor change. Some expense will be incurred by handlers and producers in adapting to the new system. However, the benefits to the industry in the affected areas of adopting a uniform multiple component pricing system outweigh the one-time costs of its adoption. The implication that everyone connected with the dairy industry must adopt this system is not correct. Pounds of milk must still be accounted for under the multiple component pricing system. For example, nothing in this decision would prevent a handler from continuing to pay haulers on a hundredweight basis. No testimony at the hearing from witnesses that have producers pooled under Federal orders that have already adopted multiple component pricing indicated that moving to a pricing system that prices milk components by the pound was an onerous burden. The transcript does reveal disagreement with the level of the protein price under some Federal orders with multiple component pricing, but little dissatisfaction with the system itself, nor complaints about the difficulty of switching to a component pricing system.

As to the argument that pricing protein and butterfat on the basis of price differentials would be revenue neutral, the multiple component pricing system recommended for adoption is designed neither to enhance nor reduce total producer returns. The only changes in the total pool value that may occur because of the recommended changes would result from differences in the protein and other nonfat solids content between milk pooled under the orders included in this proceeding and the milk included in the Minnesota-Wisconsin survey. In addition, some redistribution of the dollars involved in each pool can be expected between producers, and between handlers.

The proposal by TAPP and FUMMC, and the exceptions filed by TAPP and the North Dakota Milk Producers Association, to leave butterfat on a differential pricing basis and to price protein on a differential basis with a neutral range are not included in this decision. To continue to pay producers for butterfat and to add payment for protein on the ''traditional'' differential system would confuse and frustrate producers in the understanding of their milk checks. Continued use of differentials would perpetuate the volume-based pricing system with a high value on water, and would fail to give producers a true price signal of what the marketplace wants.

If, as predicted by TAPP's comments, pricing components on a per-pound basis leads to discontinued use of the M–W price, such a shift ought to be gradual enough to allow time for a new pricing structure to be developed for milk used in manufactured products. As noted in the recent M–W replacement decision, the recently-amended procedure for determining the M–W price is not considered to be a long-term solution.

The use of differentials in pricing milk components is not widely understood. There is no valid reason to continue an outmoded and confusing pricing system in valuing milk components. Pricing components on a

per-pound basis will allow producers to see clearly what components have the most value, a result which plainly fits the goal of encouraging producers to produce those components which have the highest value in the marketplace. Per-pound pricing also makes clear to producers that it is the pounds of components that result in payment, rather than the percentages of those components in milk. Producers would be better able to look at the cost of producing pounds of components, and compare those costs with possible returns. Application of a neutral zone would discourage producers from increasing protein production marginally unless such an increase would raise the protein level above the neutral range.

North Dakota Milk Producers Association objected that the reliability of testing and questions about the variance of components on a day-to-day basis would make the recommended pricing plan inaccurate. There is nothing in the record of this proceeding that provides a basis for concern about the ability of the market administrators and handlers in these marketing areas to test milk for the components that will be priced under this decision. In fact, the record indicates that producers currently are being paid on the basis of the component content of their milk.

a. *Protein*. The protein price for milk pooled under the five north central Federal milk orders should be calculated by multiplying the monthly average of 40-pound block cheese prices on the Green Bay Cheese Exchange by 1.32, without including a value for whey protein.

No opposition was expressed at the hearing to pricing protein on the basis of its value in the manufacture of cheese. The differences between participants came in determining the appropriate level of the protein price.

A proposal submitted and supported by National All-Jersey, Inc. (NAJ), and supported by a number of cooperative associations and other dairy organizations, would calculate the protein price in two parts: (1) Multiply the National Cheese Exchange monthly average 40-pound block cheese price by 1.32, and (2) add the monthly average whey protein concentrate price multiplied by .735. The sum of these two values would equal the protein price.

The NAJ proponent witness explained that one of the objectives of the NAJ proposal was to establish a protein price that was high enough to give producers an incentive to produce protein. He added that a second objective was to determine the protein price from market forces rather than as a residual value, as is used in other Federal orders. The witness explained that the 1.32 factor used in the NAJ proposal comes from the modified Van Slyke cheese yield formula that is commonly used by the industry. The 1.32 factor represents the pounds of 38-percent moisture Cheddar cheese obtained from one pound of protein with 75 percent of the protein going into the cheese.

The witness gave four reasons for using the National Cheese Exchange 40-pound cheddar block price (block price): (1) The majority of the cheese in the five Federal orders is priced using the block price as the base price, (2) the block price is used in determining the somatic cell adjustment in the Eastern Ohio-Western Pennsylvania, Indiana, and Ohio Valley orders, as well as being used in the determination of the Class 4b price in California, (3) since there is over twice as much American cheese manufactured in blocks as is made in barrels, and the Wisconsin assembly point barrel cheese price is within one cent of the block price, the block price represents a minimum cheese price, and (4) the protein price determined pursuant to this proposal gives a greater incentive to producers to produce protein and is more equitable to handlers and producers than the (lower) protein price contained in the other proposals.

The NAJ witness continued by explaining that the proposal included the value of whey protein in the protein price so that all of the protein in the milk would be accounted for. As explained by the proponent witness, the .735 factor was determined by dividing 25 percent, which is the protein left in whey after making cheese, by 34 percent, which is the percent of protein in whey protein concentrate. The resulting value, .735, is multiplied by the monthly average 34% whey protein concentrate price to yield the whey contribution to the protein price. The witness stated that the whey protein concentrate price was selected because it is a better indicator of the value of the protein contained in whey than is dry whey or animal feed whey.

An economist supporting the NAJ proposal testified that even though the butterfat price is determined at its marginal value, that is, the value of butterfat in butter, the protein price should be determined by the value of protein in the most common use of protein in the five markets included in this proceeding. The witness pointed out that the most common use of protein is in the manufacture of cheese, with 85.9 percent of the milk marketed in 1992 in Wisconsin being used in the manufacture of cheese. The witness testified that the appropriate cheese price to be used in computing the protein price was the block price because it is a ''conservative estimate of the price actually received for block cheddar cheese.'' The witness went on to explain that the reported block price is closer to what manufacturing plants receive for barrel cheese than is the reported barrel price because when the customary premiums are added to the reported barrel cheese price the result is approximately equal to the block price.

The academic NAJ witness reiterated the NAJ position that the value of whey protein should be included in the protein price because the total value of the protein in producer milk would thus be reflected in the protein price, giving producers an incentive to produce more protein.

A witness for Central Milk Producers Cooperative (CMPC) explained that the CMPC proposal would use the monthly average Green Bay Cheese Exchange barrel price (barrel price) instead of the block price, and would not include the value of whey protein. The witness for CMPC testified that the barrel price better represents the value of cheese than the block price because there is a greater volume of trading in barrel cheese than in block cheese. The resulting protein price would be lower than the protein price computed under the NAJ proposal. A witness for CMPC explained that their proposed protein price was based on the understanding that Federal order prices are minimum prices, and that the CMPC proposal, using the barrel cheese price and not including a value for whey protein, would result in a minimum price for protein.

The CMPC protein price proposal was supported at the hearing by other hearing participants, including National Farmers Organization (NFO), Kraft, Inc., Galloway Co., Wisconsin Cheese Makers Association (WCMA), National Cheese Institute (NCI), Farmers Union Milk Marketing Cooperative (FUMMC), and the Trade Association of Proprietary Plants (TAPP). A witness for NCI explained that if the protein price is set at too high a level, cheese manufacturers would experience a declining gross margin as the price for protein increases above the return the plant can obtain from additional protein. He explained that this would be the case with the protein price as proposed by NAJ, but not with the NCI and CMPC proposed protein price.

Other witnesses supporting a lower protein price than that proposed by NAJ explained that protein should not be priced at a high level because the higher

price may disadvantage handlers who do not manufacture cheese. They testified that the higher protein price would not be recoverable in certain products such as nonfat dry milk, condensed milk, or certain Class II products, and that even though the lower protein price still may not be recoverable, it offers the best alternative.

The Galloway witness stated that if a multiple component pricing plan that derives a protein price from a cheese market value were adopted, the protein price should represent a minimum value, should be based on the barrel cheese market, and should not include a value for whey protein concentrate. He argued that such a price would have the impact of minimizing the difference between the protein and other solids prices.

The TAPP/FUMMC witness testified that protein should be priced at a level somewhat below its full value in cheddar cheese and whey for several reasons. He said that too high a protein price could invite the use of non-dairy protein, whey solids, and casein, and thereby cause an increase in the production of imitation cheese. He also said that since some Class II and III products do not recoup as much value from high protein milk as cheese and cottage cheese, the protein price should be set at a level less than its full value for cheese. The witness expressed concern that too high a protein price could result in a zero value for the residual component, or other solids. According to the witness, a zero value for the residual would fail to reflect a realistic value, and would not cover a make allowance.

In the post-hearing brief filed by NAJ, the position of using a ''justifiably high'' protein price to send a signal to producers that protein is the most valuable component in milk was reiterated. In post hearing briefs filed by CMPC, NFO, Kraft, NCI, TAPP and FUMMC, Anderson-Erickson (A–E), and AMPI North Central Region, the computation of the protein price as proposed by CMPC was supported. The reasons given in testimony for using a lower protein price than that proposed by NAJ were reiterated in briefs. In addition, A–E, Kraft and AMPI North Central Region argued that the difference between the barrel cheese price and the block cheese price is due to the cost of packaging and other nonmilk factors, and therefore the barrel cheese price should be used for determining the protein price.

In pure economic terms the price of a product represents the supply and demand for that product as affected by place, form, and time. The problem with determining a price for protein contained in milk is that the protein is not marketed as a separate unique product, but is marketed as an integral part of both fluid and manufactured dairy products. Therefore, in determining an appropriate protein price, the value of protein in dairy products is determined by using the value of a product whose yield is a function of the protein content of the milk. At this point in time no attempt is made to reflect the protein content of milk in the value of milk used for fluid use. For this reason, the component pricing plan recommended in this decision does not apply to milk used for Class I purposes.

The level of protein in milk does have a measurable affect on the value of milk used for manufacturing. This value varies among the diverse manufactured products because of differences in the market values of manufactured dairy products and in the contribution made by protein to various finished products. For instance, testimony at the hearing showed that for a one-pound change in protein in the manufacture of cheddar cheese there is a 1.32 pound change in the quantity of cheese produced, whereas in the production of milk powder a one-pound change in the level of protein would change the amount of powder produced by approximately one pound. Since the vast majority of milk in the five orders included in this hearing is used to manufacture cheese, the protein price will be based on the contribution made by protein in the manufacture of cheese.

The 1.32 factor used in both methods proposed for the computation of the protein price for these five orders is derived from a modified Van Slyke cheese yield formula, where the casein is assumed to be 75 percent of the protein and the moisture content of the cheese is 38 percent. Assuming the butterfat is constant, a change of protein by one pound in this formula will change cheese yield by 1.32 pounds. Therefore, the 1.32 factor is appropriate for determining the order protein price.

In determining the level of the protein price, the question of whether to use the average block price versus the average barrel price is a lesser issue than the question of whether or not whey protein should be included in the computation of the protein price, as proposed by NAJ. The average difference between the Green Bay Cheese Exchange average block price and average barrel price during 1992 and 1993 was $.0388 per pound. Multiplying this difference by the 1.32 factor results in an average difference of $.05 per pound of protein between the protein prices derived from the barrel and the block cheese prices. Over the same 2 years the inclusion of whey protein in the computation of the protein price would have increased the protein price by an average of $.4265.

The principal issues that must be addressed in determining the computation of the protein price are the factors that must be included to arrive at a price that most accurately reflects the value of protein in milk. In addition, the effect of the level of the protein price on the other nonfat solids price must be considered. Since the other nonfat solids price is computed as a residual of the Minnesota-Wisconsin price, the other nonfat solids price is inversely related to the protein price. In determining an appropriate protein price and other nonfat solids price, the effects of both prices on payments to producers and margins to handlers buying milk must be determined.

Inclusion of a protein price and an other solids price in determining payments to producers gives producers an incentive to increase their production of nonfat solids, especially protein. There was no evidence in the hearing record to indicate the cost to producers of increasing the protein content of milk. It is therefore difficult to determine what the absolute level of the protein price, or its relative level to the butterfat and other solids prices, must be to encourage producers to increase the protein content of milk.

On average for the 21 months of data available in the record the protein price recommended for adoption in this decision, at $1.6851 per pound of protein, is twice both the $.6379 per pound average other solids price and the $.8374 per pound average butterfat price. Certainly, pricing protein at double the price of the other components in milk gives producers a clear message that protein is the component most desired in the marketplace without over-valuing that component. The significant difference in prices between protein and the other nonfat solids and butterfat components should give producers an incentive to increase protein output.

Testimony by several proponents of component pricing explained that component pricing would be more equitable to handlers than the current skim-butterfat pricing system. The proponents explained that the increased equity would be due to handlers paying for milk based more closely on its economic value to them. This increased equity is reflected in a narrower spread in margins between handlers making cheese from low protein-low solids milk versus handlers making cheese from high protein-high solids milk. Several

exhibits showed that handlers using ''average'' milk would experience little if any change in their net margins. However, handlers using low-testing milk would experience a higher net margin than under the present pricing plan, while handlers using high-testing milk would experience a lower net margin. This result, the narrowing of handlers' net margins when compared to the skim-butterfat pricing system, would occur no matter which of the proposed pricing plans is used to price the components.

Analysis of data presented at the hearing, using price computations based on each of the proposals and averaged over the 21 months of data included in exhibits, shows a range of net manufacturing margins for cheese using the recommended pricing system of $1.57 per hundredweight compared with the $3.34 range in cheese manufacturing margins per hundredweight of milk purchased attributable to the current skim-butterfat pricing system. The three component pricing plans discussed at the hearing would result in ranges in net cheese manufacturing margins of $1.16 per hundredweight for the NAJ proposal, $1.62 per hundredweight for the CMPC proposal, and $1.70 per hundredweight for the NCI proposal.

Even though the NAJ proposal yielded the smallest spread in net margins, further analysis of the NAJ results shows that the net margins increase and then start to decline. The decline in margins occurs when there is not enough butterfat in the milk to fully utilize the protein available, thus reducing the increase in cheese yield as protein content continues to increase. Accordingly, if the price of protein is greater than the increased return from cheese, the net return will start to decline.

The decline in net returns under the NAJ proposal indicates that the NAJ proposal would overprice protein, at least when there is not enough butterfat to fully utilize the protein. The result is that the marginal return using the NAJ proposal peaks within the protein and butterfat range of average milk while the marginal return using the protein and other solids price as recommended in this decision continues to increase, although at a decreasing rate. A mandated pricing system should not set prices at levels that result in a declining marginal return, particularly when the decline occurs at or near average market component levels. Therefore, the whey protein factor should not be included in the computation of the protein price.

Exceptions to the recommended protein price reflected the positions that the respective parties expressed at the hearing and in post-hearing briefs. NAJ and Swiss Valley reiterated their position that the protein price should be computed by multiplying the block cheese price by 1.32 and adding the result of multiplying the whey protein concentrate price by .735. They stated that the higher protein price that would result from this computation is appropriate since protein is the highest-valued component in milk. They suggested that even though the recommended decision was theoretically correct in its analysis, the analysis was flawed because of the assumption that butterfat could be a limiting factor in the yield-determining role of protein. They also pointed out that by using a higher protein price the resulting other solids price would be closer to the market value of lactose, the main component in the other solids.

Although a manufacturer could purchase additional sources of butterfat under the NAJ/Swiss Valley scenario, the cost would not be the same as the original source of butterfat and would therefore have to be included in the analysis of the manufacturer's returns. Since no data was included in the hearing record to undertake this analysis, the effect of the purchase of additional butterfat on net margins was not computed. However, since the decline in net margins under the NAJ proposal begins in the range of average testing milk, it is appropriate to adopt a protein price that does not include the value of whey protein.

CMPC, Mid-Am, WCMA, Dean Foods, Kraft, NFO, Independent Milk Producers Cooperative, and Lakeshore Federated Dairy Cooperative also opposed the recommended protein price computation in comments filed in response to the recommended decision. They specifically opposed the use of the block cheese price for computing the protein price. Their main objection was that a protein price computed on the basis of the block cheese price is not the lowest possible protein price that could be adopted based on the proposals included in the notice of hearing. Their exceptions reiterated their position that Federal order prices should be minimum prices. Their comments also suggested that use of a lower protein price and a correspondingly higher other solids price would result in smaller changes in payments to producers.

Kraft, A–E and TAPP argued in exceptions that since the only difference between the block and barrel cheese prices is packaging, the higher protein price resulting from the use of the block cheese price in the protein price computation is not warranted.

The monthly average price for 40-pound block cheddar cheese on the National Cheese Exchange in Green Bay, Wisconsin, is the appropriate price to use for determining the protein price. Use of the block price results in producers receiving a higher price for protein than if the barrel price were used without handlers incurring any significantly higher cost for milk. In addition, although the record showed that more cars of barrel cheese were sold on the Exchange than block cheese, the predominant cheese form in which American cheese is manufactured in the five-market region is in 40-pound or 640-pound blocks.

The price difference between block and barrel cheese may be due to packaging and other nonmilk factors. However, the protein price must be established at a level that best meets the needs of all concerned. The block cheese price should be more effective than the barrel price in establishing a sufficiently high protein price to accomplish the goal of encouraging producers to produce protein without having a detrimental impact on handlers, and does result in a narrower range of manufacturing margins for cheese.

Over the period January 1992 through September 1993, a protein price computed by multiplying the block price by 1.32 would have resulted in an average protein price of $1.6851 per pound. The CMPC and NCI proposals, using the barrel cheese price, would have resulted in an average protein price of $1.6337 per pound of protein over the same time period. A comparison of the net margins resulting from the recommended protein price versus the CMPC and NCI proposals shows that the slightly higher protein price and correspondingly lower other solids price adopted herein have a negligible affect on net margins. In fact, the spread between the highest and lowest cheese manufacturing margin declines slightly while the margin per pound of cheese remains virtually unchanged. At the same time, the producer is paid a higher protein price and thereby has a greater incentive to increase protein production.

The question to be addressed should be the level of protein price that will best accomplish the goals of component pricing rather than the magnitude of the protein price. Analysis of the data in this decision shows that using the block cheese price results in a protein price that accomplishes three goals: (1) Components will be priced at levels that reflect their value in the marketplace,

(2) components will be priced at levels that inform producers about which component has the greatest value and that make it worthwhile to produce that component, and (3) components will be priced at a level that will return a positive result to the manufacturing industry. All three of these goals are constrained by the requirement that the total value of the component prices must be equal to the Minnesota-Wisconsin price. Further, a protein price slightly higher than one based on the barrel cheese price will result in an other nonfat solids price that is closer to the market price for lactose.

Since the protein price contained in this decision will be only 5 cents greater than the price that would be computed using the barrel cheese price, rather than the 43-cent difference proposed by NAJ (using the whey protein price), the impact on producers should be very similar to the results shown in the exhibits presented by CMPC.

b. *Other nonfat solids*. The balance of the M-W price, after the values of protein and butterfat are removed, should be priced on the basis of ''other nonfat solids.'' The other nonfat solids price per pound will be computed by subtracting from the M-W price, at test, the butterfat price times the butterfat test of the milk in the M-W price survey and the protein price times the protein test of the milk in the M-W price survey. Because the computation of the other solids price is based on a residual value, the other solids price could be negative without further adjustments. Therefore, if computation of the other solids price results in a negative price, the protein price will be adjusted (downward) to result in a zero value for the other solids price.

As a residual, a NAJ witness stated, the other nonfat solids price would represent the value of lactose and ash, which are the primary constituents of the other nonfat solids, and the difference in value between a competitively set price for milk, the Minnesota-Wisconsin price, and the value of that milk based strictly on product prices.

An expert witness for NAJ testified that a higher price for other solids than would be computed by using a protein price lower than that proposed by NAJ was not justified because a higher other nonfat solids price would defeat the purpose of multiple component pricing: to give producers an economic incentive to increase the protein content of their milk. The witness also explained that since the ''other nonfat solids'' consist primarily of lactose, for which there is a limited market and cheaper substitutes, there is no reason to have a high other nonfat solids price.

A witness for CMPC explained that the CMPC proposal would result in a higher price for other nonfat solids than the NAJ proposal. The witness testified that reduced emphasis on the protein price and increased emphasis on the other solids price would reduce the impact of multiple component pricing on handlers and producers. The witness observed that the average difference in handlers' cost of milk between the current skim-butterfat pricing system and the CMPC proposal was less than one cent per hundredweight, while the NAJ proposal would result in a difference of slightly over three cents per hundredweight.

The CMPC witness pointed out that the same relationship was applicable to returns to producers. In fact, the witness stated, when comparing the effect of the current skim-butterfat pricing system on handlers' obligations with both the NAJ proposal and the CMPC proposal, there is a narrower spread from the highest difference to the lowest difference and a smaller standard deviation with the CMPC proposal than the equivalent comparisons with the NAJ proposal.

An alternative residual price was proposed by NCI and supported by Kraft. A witness for NCI testified that instead of placing the residual value on the other nonfat solids, the residual value should be placed on the remaining pounds of fluid milk. The witness explained that this residual fluid price would be calculated by subtracting the value of 3.5 pounds of butterfat and the value of the protein based on the protein test of the milk in the Minnesota-Wisconsin price survey from the Minnesota-Wisconsin price. The resulting value would be divided by 100 minus 3.5 minus the protein test of the milk in the Minnesota-Wisconsin price survey.

The NCI witness testified that placing the residual value on other nonfat solids would yield an ''other nonfat solids'' price that could not be recovered in the marketplace. In addition, he stated, although the butterfat price is based on the butter market and the protein price would be based on the return to cheese manufacture, the other nonfat solids price would have no relationship to any particular established market or component. The witness also testified that since another nonfat solids test would not be needed for the NCI proposal, administration of the pricing plan would be easier and less expensive than the other pricing proposals.

NCI, Kraft and A-E excepted to the use of other nonfat solids as the pricing factor to represent the residual value of the M-W price. NCI suggested that the same argument used in the Southern Michigan revised recommended decision (59 FR 64464) for the use of a fluid carrier component to represent the residual value of the M-W price be used in this final decision. Kraft and A-E also supported the use of a fluid carrier component. In its exceptions, Kraft stated that use of a fluid carrier would moderate pricing extremes between producers, and that use of other solids to price the residual value of the Minnesota-Wisconsin price overprices lactose and fails to recognize the value of the fluid portion of milk.

The proposal by NCI to place the residual value on a ''fluid carrier'' component has some merit in that it does not try to apply the residual value to a component such as other solids, on which the market may not place a value. The major drawback to the NCI proposal is that it ignores one of the components of milk, other nonfat solids, which is composed of lactose and ash.

Until a component pricing plan is developed that does not tie the total value of the components to the M–W price, there will be a need to adjust the price of at least one of the components from a product-based value. As explained in this decision, and in the comments and exceptions filed by various parties, the M–W price consists not only of the base value of milk, but also various premiums, different pricing systems, and probably most importantly, competition for milk supplies in Minnesota and Wisconsin. Even though good arguments can be made for using a fluid carrier to represent this residual value, the record of this proceeding supports the use of other nonfat solids to represent the residual value.

Although the other nonfat solids do not have as much market value as either butterfat or protein, they are an important component of milk. If a multiple component pricing system is to be effective it should price as many of the components in milk as possible, preferably based on the value of those components in the marketplace. There is, however, no readily available measure of the market value of the other nonfat solids. Since there was no testimony or any justification in the record for departing from the Minnesota-Wisconsin price as a basic price for milk, at least one of the components in the payment plan must represent the difference between a competitively-set pay price (the M–W) and the product-derived component prices. This residual value therefore represents not only the value of the lactose and ash, but also equates the

component values, some of which are determined by their market value, with a competitively set producer pay price.

The prospect of lactose being added to milk by producers for the purpose of benefitting from the other solids price was discussed by several hearing participants. The incentive to adulterate milk with added lactose should be no more of a problem than the current incentive to adulterate milk with water. Testing to determine whether lactose has been added should, in fact, be easier than testing for water since it would be part of the testing necessary to determine producers' payments. In addition, added lactose can be detected during normal testing procedures currently conducted on milk.

NCI's concern that testing for total solids would increase handlers' costs and difficulty of testing was not established in the hearing record. In fact, testimony indicated that many handlers are already testing for total solids. Hearing testimony also showed that the testing for total solids is as accurate or more accurate than testing for butterfat or protein. In addition, the infrared machines that are used by most laboratories will test for total solids at the same time the butterfat and protein tests are done. Therefore, there should be no significant increase in testing cost or testing difficulty with the implementation of the component pricing plan incorporated in this decision.

LOL, in its comments on the recommended decision, pointed out a ''flaw'' in the formula used to compute the other solids price. LOL noted that the M–W price is adjusted to a 3.5 percent butterfat test, but that the skim component tests are left ''at test.'' What this means is that the protein and other solids tests do not reflect the quantity of protein or solids in milk of 3.5 percent butterfat, but rather the quantity of protein and solids in the milk at test. Therefore, the value of the protein that is deducted to arrive at the residual value for computing the other solids price may be incorrect, thus resulting in an incorrect other solids price. The problem could be magnified because the other solids test does not reflect the correct quantity of other solids in the remaining skim milk. The effect of this ''flaw'' is relatively small; however, this decision adjusts the computation of the other solids price to eliminate the shortcoming observed by LOL.

c. *Butterfat*. The value of butterfat in the amended orders will be the same as under the current orders. There was no proposal or testimony to change the way butterfat currently is valued. One expert witness testified that the current system of basing the value of butterfat on the value of butter is proper.

This decision continues the historical relationship of the values of butterfat and butter. The difference between the pricing of butterfat in the amended order and the current order is due to the way that value is expressed. Currently the value of butterfat is expressed as a differential; that is, the difference in value between 0.1 pound of butterfat and 0.1 pound of skim milk. The amended order will express the value of butterfat on the basis of a price per pound. Whichever method is used, the total value of butterfat in milk is the same. However, by expressing the value on a per-pound basis instead of a differential, the objective of demonstrating clearly to producers where the value is in milk is easily achieved.

As proposed, the butterfat price per pound in the amended order will be determined by multiplying the butterfat differential by 965 and adding the Class III price. The resulting price per hundredweight would then be divided by 100 to give a price per pound of butterfat. For example, if the result of the computation is $0.73085, the announced butterfat price would be $0.7309 per pound of butterfat.

d. *Miscellaneous*. The three component prices: butterfat, protein, and the other solids, will be expressed on a per-pound basis with four places to the right of the decimal. Analysis has shown that by expressing these prices to the nearest one-hundredth of a cent, the accuracy of the prices is significantly enhanced over expressing the prices to the nearest cent. Additionally, the difference between what is paid into the producer settlement fund and what is drawn from the producer settlement fund is much closer to zero than when prices are rounded to the nearest full cent.

In contrast to other orders that have multiple component pricing provisions, this decision incorporates only one protein price as well as one other nonfat solids price. The pooling of the components to include the Class I skim portion is incorporated within the computation of the producer price differential. This feature of the pricing plan allows for the elimination of separate handler and producer protein prices and separate handler and producer other solids prices, and resulting confusion over which price, handler or producer, should be used when. In addition, a handler's per-pound price for protein or other solids is the same whether the handler is buying milk from producers or from other handlers.

The producer price differential, which represents the additional value of Class I and Class II milk in the pool and any positive or negative effect of Class III–A, will be determined by computing for each handler, and then accumulating for all handlers, the differential value (from Class III) of the Class I, Class II, and Class III–A product pounds. The differential value is adjusted, when appropriate, for shrinkage and overage, inventory reclassification, receipts of other source milk allocated as Class I, receipts from unregulated supply plants, location adjustments, and, in the Chicago Regional order, transportation and assembly credits.

For the purpose of eliminating differences between handler and producer component values, the value of the Class I skim milk and the values of the protein and other solids contained in the skim milk allocated to Class II and Class III (and somatic cell adjustments) will be added to, and the values of the protein and other solids contained in all producer milk (and somatic cell adjustments to producer milk) subtracted from, the differential pool. The accumulated total for all handlers is then adjusted by total producer location adjustments and one-half the unobligated balance in the producer settlement fund. The resulting value is then divided by the total pounds of producer milk in the pool, and an amount not less than four cents nor more than five cents is deducted. The result is the producer price differential to be paid to producers on a per hundredweight basis.

It is possible for the producer price differential to be negative. A negative producer price differential can result for two reasons. Any of the Class I, II, or III–A differential prices may be negative and/or the minus adjustments may be large enough to offset any positive contribution from the differential price. A negative producer price differential would be equivalent to a uniform price less than the Class III price.

An issue that was not directly addressed in this proceeding concerned testing for protein. The five orders included in this hearing currently base protein testing on the standard Kjeldahl method, which tests for nitrogen and then converts the nitrogen result to protein. Since there is a certain amount of free nitrogen in milk this test somewhat overstates the protein content of milk. Recent developments in testing allow for testing for true protein which is a more accurate reflection of protein content. In no way does this decision mandate a specific testing procedure. However, when (or if) the industry does move to testing for true protein, this

decision should not be viewed as a hindrance to that conversion. At the time a change to testing for true protein may occur, a change in the 1.32 factor may be necessary.

4. *Somatic Cell Adjustment.* The producer price differential paid to each producer should be adjusted on the basis of the somatic cell content of the producer's milk. In a modification from the recommended decision, handlers' value of milk used in Class II and Class III, but not in Class I, also would be adjusted for somatic cell count (SCC). The value adjustment per hundredweight for each 1,000 somatic cells would be determined by multiplying .0005 times the monthly average National Cheese Exchange 40-pound block cheese price. Each producer's monthly average SCC, in thousands, would be subtracted from 350 and multiplied by the value adjustment per 1,000 somatic cells. The difference between somatic cell adjustments to handler value and to producer value will be included in the computation of the producer price differential.

A wide range of somatic cell or quality plans were included in the notice of hearing and at the hearing itself. In general, all parties agreed that high-quality milk is important to all segments of the dairy industry. The major differences between the parties arose over the questions of how and whether quality and/or somatic cell adjustments should be included in the Federal order program.

A witness expert in the field of milk testing and quality testified about the influence somatic cells have on milk and the resulting affect on products made from milk. The witness explained that in normal healthy cows the somatic cell count is around 50,000. When an infection occurs in the udder of the cow white blood cells enter to fight the bacterial infection. The SCC thus increases with the increasing number of white blood cells. In fact, white blood cells and somatic cells are synonymous in this context. The witness continued by explaining that white blood cells contain enzymes that are designed to break down the cell walls of the bacteria that are infecting the udder, but do not distinguish between milk protein and bacteria. As a result, milk protein is also degraded. The witness also stated that the enzyme causes some deterioration in milkfat. The witness continued by explaining that these white blood cells also cause to be activated a proteolytic enzyme that is present in all milk.

The expert witness went on to explain that casein, which is the functionally important protein in milk, is broken down into smaller protein chains that cannot perform the same functions as the casein. In fact, the witness explained, the destruction of the casein affects all dairy products that rely on casein for structure or function. These products include cheeses, whipped cream, yogurt, ice cream, and condensed and dry products used in the manufacture of other products in which casein is a functional necessity. The witness also explained that higher SCC milks have a tendency to have a faster increase in ''acid degree value'', which is a measure of rancidity and off flavors, than milks with low SCCs. The witness testified that most of the damage occurs in the udder of the cow, where conditions are ideal for the various enzymes to work. Once the milk is removed from the udder and cooled and stored properly, further deterioration does not stop but is slowed down significantly, and further damage is minimized.

The expert witness discussed the effect that somatic cell counts have on the manufacture of various dairy products, specifically cheese. He explained that high SCC milk results in lower cheese yields as well as problems with moisture control and the activity of the starter culture. The increased somatic cells result in less casein in relationship to the total protein so that less cheese is produced than would be indicated by the amount of protein present. The degraded protein ends up in the whey with the rest of the whey proteins. The witness explained that in studies using individual cow's milk cheese yield would drop dramatically as the somatic cell count went above 100,000, with the yield staying fairly constant as the somatic cell count climbed to 1,000,000.

The witness pointed out that the cheese yield effect of somatic cells differs when bulk tank milk is used instead of an individual cow's milk. He explained that in the case of bulk tank milk the relationship between cheese yield and somatic cell counts would be linear, with cheese yields declining as SCCs increase. The witness stated that the linear relationship is caused by the weighting of the SCCs in the bulk tank. Bulk tank tests are weighted averages rather than simple averages. For example, if 100 pounds of milk with a somatic cell count of 50,000 and 400 pounds of milk with a somatic cell count of 250,000 are added to the bulk tank the somatic cell count would be a weighted average of 210,000 and not the simple average of 150,000.

The witness also testified that the effect of somatic cell levels on fluid milk products is reflected in higher acid degree values that indicate rancidity and off flavors, resulting in shorter shelf life.

The expert witness testified that routine testing for somatic cells is conducted using a Foss-O-Matic infrared analyzer. The reference method for testing is the direct microscope somatic cell count in which the sample is stained and the somatic cells are counted using a microscope. The witness explained that if the electronic instruments are calibrated to the same reference samples the resulting test values and standard deviations should be in close agreement. The witness concluded that on a relative basis the results should be close to what would be obtained using other analytical tests.

The notice of hearing contained a proposal by CMPC to include an adjustment for somatic cells. However, at the hearing, a witness for CMPC explained that CMPC had decided neither to support nor oppose the inclusion of a somatic cell adjuster in the amended orders. The CMPC witness testified that the individual members of CMPC were free to support or oppose any of the somatic cell proposals as they saw fit.

As originally proposed by CMPC, the somatic cell adjustment would be computed by multiplying the National Cheese Exchange barrel price times .0005. The resulting quantity would be multiplied by 500 minus the somatic cell count of the milk, in thousands. The resulting value would be applied on a per hundredweight basis. As explained by a witness for CMPC, the proposed somatic cell adjuster would apply to all producer milk, including that purchased by Class I handlers. The witness went on to explain that the effect of somatic cells on the value of producer milk and milk used in Class II and Class III would be included in the computation of the producer price differential. A somatic cell adjustment on Class I milk would not be included in the pool, and therefore would not affect Class I handlers' cost of milk.

A witness for WCMA quoted extensively from the MCP recommended decisions for the Indiana, Ohio Valley, and Eastern Ohio-Western Pennsylvania milk marketing orders, and for the Michigan milk order, supporting the inclusion of an adjustment for somatic cells in Federal orders. The witness supported the CMPC proposal, but suggested that the somatic cell adjustment be applied to all milk; that is, Class I milk would not be exempted from a somatic cell adjustment. In addition, he proposed that the somatic cell adjustment be

applied to the protein price rather than on a hundredweight basis.

A witness for TAPP and FUMMC expressed support for including a somatic cell adjustment in the amended orders. The TAPP-FUMMC brief also supported such a provision. The witness stated that a somatic cell adjustment would benefit producers, handlers, and consumers by increasing the volume of milk marketed, improving yield, and supplying consumers with more nutritious, better quality dairy products. The TAPP/FUMMC witness explained that their proposal would have a neutral range of 301,000 to 400,000 somatic cells with a one-cent positive adjustment for each 50,000 somatic cell count below the neutral range up to a maximum of a six cents as the somatic cell count declined, and a one cent negative adjustment for each 50,000 somatic cell count above the neutral range up to a maximum of ten cents as the somatic cell count increased. The TAPP/FUMMC witness testified that under their proposal the somatic cell adjustment would apply to all producer milk, milk used in Class III, and, if the plan is to be revenue neutral, also to milk used in Class II.

A witness for Swiss Valley Farms Company (Swiss Valley) testified in support of including additions and subtractions for somatic cells in the amended order. The Swiss Valley witness explained that somatic cells add proteolytic and lipolytic enzymes to the milk, as well as a plasmin enzyme that is extremely heat stable, such that it is not deactivated during pasteurization. Therefore, the enzyme continues to degrade the milk during storage. The witness added that low SCC milk is important to the Swiss Valley bottling operations because it results in fluid milk products of improved flavor, and to their cheese-making operations because of the resulting higher casein and lower whey protein content of the milk, which increases manufacturing returns.

The Swiss Valley witness proposed that the somatic cell adjustment begin at 400,000, with a positive adjustment as the SCC declines, and a negative adjustment as the SCC increases, from that level. The adjustment would be five percent of the National Cheese Exchange block price per 100,000 somatic cells. The Swiss Valley witness explained that the adjustment for somatic cells should apply to all producer milk and that Swiss Valley would support a somatic cell adjustment on Class II and Class III milk for the handler.

In its post-hearing brief, Swiss Valley reiterated the testimony of its witness in favor of including an adjustment for somatic cells in the amended order. Besides supporting the position of the Swiss Valley witness, Swiss Valley expressed general support for a somatic cell adjustment.

Testimony by a fluid processor witness indicated that the handler pays a quality premium when buying milk from producers and specifies minimum quality standards on purchased tanker milk.

A witness for Mid-America Dairymen, Inc. (Mid-Am), testified that Mid-Am favored the inclusion of an adjustment for somatic cells in the amended order. The witness quoted from the Final Decision of the Indiana, Ohio Valley, and Eastern Ohio-Western Pennsylvania proceeding to support the position of Mid-Am that an adjustment for somatic cells should be included based on the effect somatic cells have on all milk. The witness explained that quantifying the adjustment on an incremental basis was difficult, and since not all milk is used in the manufacture of cheese a moderate adjustment rate should be used. The witness explained that the Mid-Am proposal would apply the somatic cell adjustment to all producer milk, on a hundredweight basis, with a positive adjustment for a somatic cell count below 400,000 and a negative adjustment for SCCs above 400,000.

The witness explained that under the Mid-Am proposal, the somatic cell adjustment would be computed by subtracting the monthly average somatic cell count (in thousands) of the producer from 400 and then multiplying the result by the National Cheese Exchange monthly average barrel cheese price multiplied by .0005. He stated that since the somatic cell adjustment would be included in the computation of the producer price differential, on the producer side only, the total size of the pool would not change but individual producers would receive more or less, depending on whether their milk had a somatic cell count above or below the average SCC of the market. The Mid-Am witness continued by explaining that the Mid-Am proposal would be a redistribution of money from high somatic cell testing producer milk to the lower somatic cell testing milk, since there would be no additional money in the pool from the somatic cell adjustments.

Instead of supporting the inclusion of somatic cell adjustment provisions in the five Federal orders, witnesses testifying on behalf of Land of Lakes, Inc., and NCI supported those organizations' proposals to allow each handler to submit a somatic cell or quality adjustment plan for payments to its own producers to the market administrator.

A witness for LOL testified that with the LOL proposal a handler could reduce a producer's payment by up to ten percent from that required by the order if other producers of the handler received positive adjustments to their payments, as long as the total payments were equal to at least the minimum total order payment requirements. The witness explained that LOL's proposal does not contain specific criteria for quality and/or volume adjustments. Each handler would submit an individual quality and/or volume adjustment plan to the market administrator which the handler would be required to adhere to until a new plan would be submitted. The witness testified that there is general agreement among handlers for the need to adjust payments for milk based on quality and volume. The witness continued by arguing that since the industry has not yet reached a consensus on how to adjust for quality and volume, it would be appropriate to allow each handler to develop its own quality and volume plan with the approval of the market administrator.

A witness for NCI testified that even though somatic cells affect the quality of milk, particularly in the manufacture of cheese, it is difficult to place a value on their effect. The witness explained that the variability in somatic cell levels from day to day and producer to producer makes determining an appropriate payment adjustment imprecise. In addition, the witness pointed out that other factors affect milk quality, and that placing a precise value on their effect is even more difficult than in the case of somatic cells. The NCI witness explained that the NCI proposal would allow each handler to establish and apply its own somatic cell adjustment schedule, with the approval of the market administrator, as long as the total payments to producers met or exceeded the Federal order minimum value. The witness explained that each handler could change its payment plan as conditions warranted.

A witness for Kraft emphasized the earlier testimony on the effect of somatic cells on milk quality and cheese yields. The witness listed several studies supporting the results testified to by the NAJ expert witness. The Kraft witness testified that Kraft has, since the early 1980's, employed a quality payment program as part of its producer payroll. The witness went on to state that the plethora of somatic cell payment programs in use in the industry is strong evidence of the industry's recognition that somatic cells

play a major role in milk quality. The Kraft witness explained that, in order of preference, Kraft supports the proposal submitted by NCI, followed by LOL's proposal and the TAPP/FUMMC proposal.

Kraft, in its post-hearing brief, reiterated its support for a somatic cell adjustment to be included in the amended order. Kraft's brief did not support a particular adjustment plan but preferred the LOL–NCI concept. If that plan were not adopted, Kraft expressed support for the proposal by Mid-Am or the original CMPC proposal. A brief largely reiterative of NCI testimony was filed on behalf of NCI with the Dairy Division rather than the Hearing Clerk, and was received more than 3 weeks after the extended due date for filing briefs. The brief is not considered in this decision.

In the Anderson-Erickson Dairy Company (A–E) post-hearing brief, A–E opposed the application of an adjustment for somatic cells to Class I milk. They contended that the Class I handler is unable to recover the added cost of lower somatic cell count milk from the retail market. This position was supported in the post-hearing brief filed by Lamers Dairy and Hansen Dairy (Lamers). Lamers pointed to testimony that indicated that the monetary effect of somatic cells on Class I milk could not be quantified as it could be with the manufacture of cheese.

NFO, in its post-hearing brief, opposed the inclusion of any somatic cell adjuster in the recommended order. NFO expressed the opinion that support for a somatic cell adjuster was rather weak, with none of the positions presented having strong support. As an example, the NFO brief pointed to the neutral position taken by CMPC at the hearing after including a somatic cell adjuster in the original CMPC proposal. The NFO brief continued by explaining that testimony at the hearing indicated that the relationship between somatic cell levels and economic return is not a clear and definite relationship. The NFO brief went on to point out that there was no consensus at the hearing on how to apply a somatic cell adjuster.

There is ample testimony and evidence to support the inclusion of a somatic cell adjuster in these amended orders. The recommended decision proposed that a somatic cell adjustment be applied to all producer milk, regardless of the class in which it is used. Such an application would have avoided including the difference between the handler and producer somatic cell adjustments in the computation of the producer price differential; a procedure that, during some months, could result in a significant adjustment in the producer price per hundredweight. The recommended application also would have assured that all handlers' obligations would reflect the quality of the milk they receive.

The somatic cell adjuster per hundredweight per 1,000 somatic cells will be calculated by multiplying .0005 times the monthly average National Cheese Exchange 40-pound block cheese price. To determine the value for an individual producer, the producer's monthly average somatic cell count (in thousands) will be subtracted from 350 and multiplied by the somatic cell adjuster. The value of Class II and Class III milk will be adjusted by the same formula. However, for the purpose of adjusting handlers' values, 350 will be subtracted from the best available source of the somatic cell test. This information may be, but would not necessarily be limited to, load tests, farm tests, and monthly average tests.

The value of the somatic cell adjustment will be applied on a per hundredweight basis in the handlers' payments to producers and in payment for Class II and Class III milk. Somatic cell counts will be reported with the report of receipts and utilization for all producer milk and on Class II and Class III milk.

The application of the somatic cell adjustment contained herein will promote orderly marketing. As pointed out by several witnesses testifying at the hearing, producers in these markets are faced with a wide array of quality premium programs. These programs have no standard basis or standard value that is applied between handlers. Therefore a producer is faced with trying to decide which premium program will give the producer the greatest return without a standard with which to compare. Inconsistent premium programs also result in producers with identical milk receiving different prices for that milk depending on which handler is procuring the milk. The inclusion of this somatic cell adjustment will tend to effectuate the declared policy of the Act by encouraging orderly marketing through the standardization of the basis for payment on the level of somatic cells in the milk and the standardization and checking of the testing and test procedures used for determining the somatic cell counts.

As was stated earlier, all parties agreed that high quality milk is important to all segments of the dairy industry. In fact, there was little opposition at the hearing to the inclusion of an adjustment for quality in the amended orders. Even though testimony indicated that there are other quality factors that are important in overall milk quality, there was no determination of their effect on milk quality or any attempt to compute a relevant associated value. Therefore, somatic cell count will be used as the quality adjustment factor in this decision.

There are two basic reasons to apply the somatic cell adjustment rate on a hundredweight basis rather than to adjust the protein price. First, the somatic cell adjustment reflects the quality of milk in many uses rather than just cheese, and second, application of the somatic cell adjustment on a hundredweight basis makes it very clear to producers and to handlers that quality affects milk used in all products. Although testimony clearly showed that somatic cells affect the quality of milk in all uses, a value determined on the basis of the effect of somatic cells on cheese reflects the most prevalent use of milk in these markets and is the easiest way to determine a value for payment to producers.

A lack of agreement among hearing participants occurred in trying to determine the application of a somatic cell adjustment. There was a general consensus that an adjustment should be made in the producer pay price for quality and/or somatic cells. The rate at which such adjustment should be made varied by proposal, but was tied to the reduction in cheese yield that occurs as somatic cell counts increase. Several witnesses testified that the somatic cell adjustment rate should be set at a moderate level. Testimony indicated that most of the decline in cheese yield occurs as the SCC increases from below 100,000 to above 100,000, with a much slower decline in yield as the somatic cell count increases to one million. However, testimony also showed that declines in yield are much more linear when somatic cell tests and cheese yield studies are done with bulk tank milk than with the milk of individual cows. Several proposals suggested using a factor of .0005 times the cheese price in determining the value of the somatic cell adjustment per 1,000 somatic cells. This factor is derived from the approximately four percent decline in cheese yield as the somatic cell count increases from 100,000 to one million. This is the same adjustment that is used in other Federal orders in which a somatic cell adjuster is included.

The formula used to determine the somatic cell adjuster reflects the changes in the yield of cheese as the levels of somatic cells change. The formula also ties the adjustment to the

value of the milk by using the block cheese price to determine the value per 1,000 somatic cells. However, since record evidence clearly shows that the effect of somatic cells on Class I and Class II products is related more to the quality of the finished product than to the yield of the product, the formula should reflect less than the full value of the effect of somatic cells on cheese yield. Using the recommended formula, the somatic cell adjustment for the average producer under the Chicago Regional order would be a plus three cents per hundredweight, far below the 25 cents per hundredweight average quality premium that is shown in hearing exhibits as being paid currently.

The corresponding somatic cell adjustments for average producers under the four orders in addition to Chicago are: Upper Midwest, zero cents; Iowa, minus one cent; Nebraska-Western Iowa, minus six cents; and Eastern South Dakota, minus three cents. The formula results in an estimated range of forty-eight cents per hundredweight from a somatic cell count of 1,000 to a somatic cell count of 750,000, or a positive twenty-two cents to a minus twenty-six cents, although there is no limit on the deduction that may be made since there is no limit on the maximum SCC in this decision.

The use of a neutral point was supported by various proponents of a somatic cell adjuster. Several others suggested a neutral range. The record contains numerous references to a neutral range or point around a somatic cell count of 400,000. One witness expressed the opinion that the base level for the somatic cell adjustment should be near the average for the five markets. Another witness explained that their proposal used 400,000 SCC because that is where their present quality program begins. Based on data included in the hearing record, the average SCC for producers whose milk is pooled under the five orders is 367,000. Therefore, a neutral point of 350,000 is appropriate. It is close to the average for the markets, and not substantially different from the values that witnesses found appropriate. Also, by using the formula included herein, proponents of both a neutral point or a neutral range are accommodated because the formula yields no value adjustment for approximately plus or minus 7,000 SCC around 350,000.

The formula will give producers an incentive to reduce their SCCs while minimizing the effect of the somatic cell adjuster on those products in which somatic cells have a quality effect rather than a yield effect.

Neither the quality proposal by LOL nor the somatic cell proposal by NCI, in which each handler would be allowed to submit an individual quality or somatic cell payment plan to the market administrator, is included in this decision. Although the Agricultural Marketing Agreement Act in 7 U.S.C. 608c(5) does allow for adjustments to minimum pay prices on the basis of quality, such adjustments should be at a uniform rate for all producers in the market. Allowing each handler to have its own payment schedule would defeat the concept of uniform pricing to producers, eliminate the purpose of allowing quality adjustments under the order, and lead to disorderly marketing. Producers with identical milk shipping to different handlers within the same market could, and probably would, have different minimum order pay prices if each handler had its own quality or somatic cell payment plan.

A number of witnesses testified that the profusion of payment plans currently in effect in the market today are causing disorderly marketing, and that one of the benefits of incorporating multiple component pricing with a somatic cell adjustment in the five orders would be to reduce or at least standardize the vast array of producer payment plans currently in effect in the region. In view of such testimony, adoption of the LOL or NCI quality adjustment proposals would serve no purpose.

Support for the inclusion of a somatic cell adjuster in the amended orders was expressed in comments filed in response to the recommended decision by several parties including LOL, Cass-Clay Creamery, Mid-Am, Grande Cheese, WCMA, Kraft, AMPI-Morning Glory Farms, TAPP, and Swiss Valley.

Mid-Am, Grande, WCMA, Kraft, and Swiss Valley expressed unequivocal support for the inclusion of a somatic cell adjuster. Mid-Am stated that higher SCCs decrease cheese yields and also affect fluid products. Grande and WCMA expressed the view that the recognition of the importance of quality is long overdue, particularly on all classes of milk, and that producers should be rewarded for producing quality milk. Kraft, in support of the somatic cell adjustment, explained that high SCCs have a direct and measurable adverse impact on cheese yields and, in fact, on all dairy products. Kraft's comments explained that even though the SCC is not the only quality factor, it is a good indicator of overall milk quality. Kraft also said that if the somatic cell adjustment is not applied to all milk, disorderly marketing could occur, with fluid handlers trying to switch supplies to take advantage of the economics of procuring a low-SCC milk supply at no additional cost.

Swiss Valley, with two bottling plants in the marketing areas covered by this decision, expressed support for the inclusion of a somatic cell adjustment. Swiss Valley particularly expressed support for the application of a somatic cell adjustment to fluid milk, stating that a somatic cell adjuster will help insure quality milk for fluid handlers that will result in improved flavor and longer shelf life for fluid milk. They explained that the inclusion of a somatic cell adjustment under the Federal order program would eliminate the wide array of somatic cell programs currently in the marketplace and that even though the somatic cell adjustment is not large it is economically sound.

The remainder of the comments favoring a somatic cell adjuster included some qualifiers or suggested modifications to the recommended decision. LOL and Cass-Clay Creamery suggested that if a somatic cell adjuster is included in the final decision, it should not apply to movements of milk between handlers but only to payments to producers. LOL added that a somatic cell adjustment on milk movements between handlers was not included in the notice of hearing.

In exceptions filed by AMPI-Morning Glory Farms, the cooperative supported the somatic cell adjuster on all milk, but suggested that the ''break point'' be at a somatic cell count of 400,000 versus the 350,000 contained in the recommended decision. AMPI also stated that there should not be a somatic cell adjuster if it is not applied to all milk, because a somatic cell adjuster on only Class II and Class III milk would cause disorderly marketing.

TAPP's exception supporting a somatic cell adjuster recommended several changes. TAPP's comments expressed the belief that the amount of the recommended somatic cell adjustment is too large, causing too great a spread in value between the lowest and highest somatic cell tests. TAPP also suggested that there be a larger neutral range, and that the somatic cell adjustment should remain constant rather than changing each month based on the cheese market.

The Milk Industry Foundation (MIF), along with many fluid handlers without plants in the affected marketing areas, filed comments opposing the inclusion of a somatic cell adjustment on Class I milk in the final decision. They all gave the same six reasons for their opposition: (1) There was not enough evidence at the hearing to support a somatic cell adjustment on Class I milk,

and, in fact, that a Class I handler testifying at the hearing opposed a somatic cell adjustment on Class I milk; (2) somatic cells are not the only quality factors that should be included; (3) a somatic cell adjustment on Class I milk would cause disruptive and inequitable marketing conditions for fluid handlers, both between and within marketing areas; (4) fluid handlers cannot recover the added cost of the somatic cell adjustment from the marketplace; (5) a somatic cell adjustment would eliminate advance Class I pricing; and (6) Federal orders should not be involved in quality issues.

Anderson-Erickson (A–E), Dean Foods, and Marigold, who are fluid handlers regulated under one or more of the affected orders, opposed the inclusion of a somatic cell adjustment on Class I milk. They gave the same arguments as MIF, et al., plus several more. A–E comments stated that a somatic cell adjustment based on the effect of somatic cells on cheese has no bearing on the effect of somatic cells on Class I milk, and therefore does not reflect an appropriate value adjustment. Marigold explained in its exceptions that there is no evidence that specific levels of somatic cells can be discerned in fluid milk by consumers, and therefore a value cannot be placed on varying levels of somatic cells in Class I milk. Dean's comments expressed the belief that value adjustments based on quality should be determined by competition rather than by Federal orders.

Wells Blue Bunny, NCI, and Independent Milk Producers Cooperative filed comments opposing the inclusion of any somatic cell adjustment in the amended order.

Lakeshore Federated Cooperative (Lakeshore), consisting of Manitowoc Milk Producers, Mid-West Dairymen's Company, and Milwaukee Cooperative Milk Producers were joined in their exceptions to the recommended decision by FUMMC, Muller Pinehurst Dairy, Prairie Farms, Woodstock Progressive Milk Producers, and the Galloway Company in opposing any inclusion of a somatic cell adjustment in this decision. In addition to the same arguments that were put forth by the fluid handlers, Lakeshore's opposition was directed toward the need for an additional cost of testing for somatic cells. Lakeshore's comments pointed out that the State of Wisconsin requires one test a month for somatic cells, which also satisfies the requirements for the PMO (Pasteurized Milk Ordinance) and IMS (Interstate Milk Shippers) certification. The comments stated that a requirement by the market administrators that producer milk be tested for somatic cells four times per month for payment purposes, or an additional 40 tests per year, would create a burden on cooperative associations that do not do so much testing at the present time. Lakeshore went on to argue that the recommended decision would conflict with state regulations with regard to somatic cells, and asserted that because somatic cell testing is adequately monitored by the states there is no need for additional monitoring by market administrators.

Lakeshore claimed that including a somatic cell adjuster would cause its members to sustain a financial loss due to the cost of testing for somatic cells. Lakeshore claimed that testing for somatic cells would increase the costs of labor, computer programming, paper work, compliance with bureaucratic regulations, and the cost of additional laboratory equipment, which could not be recovered. Lakeshore also claimed that a recent increase in the Chicago Regional assessment was due to somatic cell testing in the Indiana marketing area, but there is no record evidence supporting this claim.

Lakeshore also stated that because the relationship between cheese yields and somatic cell count is not a straight-line relationship, no value can be placed on somatic cell counts of differing levels.

FUMMC and Prairie Farms filed exceptions of their own. FUMMC expressed its opposition because its proposal for a wide neutral range where there would be no adjustment was not adopted. FUMMC also claimed that somatic cell test results are variable and inaccurate, making the recommended decision impractical and unworkable.

Prairie Farms expressed the opinion that a somatic cell adjustment would cause disorderly marketing conditions between orders with a somatic cell adjuster and those without one. Prairie Farms also expressed the belief that sanitary and quality standards are beyond the scope of Federal orders.

NFO filed exceptions opposing the recommended somatic cell adjustment in its entirety, for a number of reasons. NFO claimed that support for inclusion of a somatic cell adjustment in the Federal orders was limited at the hearing and in post-hearing briefs, and argued that major changes of the magnitude of a somatic cell adjustment have not previously been made with such limited support. NFO asserted that the premise that inclusion of a somatic cell adjuster would contribute to orderly marketing would not be fulfilled.

NFO's comments further claimed that the recommended somatic cell adjustment would result in less revenue to dairy farmers because the 350,000 base point for the adjustment is higher than average producer milk in four out of five of the affected markets. NFO argued that any somatic cell base point (the somatic cell level from which producer prices are adjusted up and down) should reflect the somatic cell count of the Grade B milk in the Minnesota-Wisconsin price survey. NFO also argued that a somatic cell adjuster would reduce over-order premiums and thus reduce dairy farmer incomes.

Finally, NFO argued that the record does not support a linear relationship between cheese yields and somatic cell counts, and that the decision did not take into account the extra cost of testing.

Although NFO's comments opposed adoption of a somatic cell adjuster, the cooperative did support application of such an adjuster to all milk, including Class I, if the somatic cell adjustment is included in the final decision.

Comments filed in response to the recommended decision contained significant support for inclusion of the somatic cell adjustment as contained in the recommended decision. The comments received also reflected substantial opposition from fluid milk handlers to the aspect of the somatic cell adjustment that would have applied to all producer milk, including Class I.

On the basis of the exceptions received, this decision has been changed from the recommended decision to include an adjustment to the value of milk based on the level of somatic cells contained in all producer milk and in Class II and Class III milk. As a result, the somatic cell adjustment will be included in the pool process, so handlers will have to report somatic cell count information with their reports of receipts and utilization.

The decision to exclude handlers' Class I milk from application of a somatic cell adjustment is based on several factors. As observed by exceptors, the hearing record contained little if any testimony or evidence to quantify the economic effect of varying somatic cell levels on Class I milk, although there was considerable testimony as to the effect somatic cells have on shelf life, off flavors and rancidity in fluid milk products. Since no specific data about the value of using high-quality milk in fluid products was presented and opposition to the application of a somatic cell adjustment on Class I milk was so strong, the somatic cell adjustment will not be applied to milk used in Class I as a result of this proceeding.

Monitoring of somatic cell testing, which already clearly affects the

payments made to most of the producers pooled under these five orders, by market administrators will assure as much uniformity and accuracy as possible in the testing procedures. Also, since 70–80 percent of the milk pooled under these orders is used in Classes II and III, application of a somatic cell adjustment to that proportion of the milk used by handlers will doubtless result in a favorable effect on the general quality of the milk in the marketing areas.

Kraft and AMP's concerns about the ability of fluid milk handlers to procure supplies of milk with low somatic cell counts at no extra cost are unlikely to materialize. According to the record, many fluid handlers already pay premiums for high-quality milk. There is nothing in the provisions of the amended orders that would prevent the continuation of the payment of such premiums. In fact, the requirement that the value of milk used in Classes II and III be adjusted for its somatic cell content will most likely necessitate equivalent payments by fluid handlers in order to assure that the supplies of milk they receive are of at least average quality.

LOL may be correct that having to account for somatic cells in transfers and diversions could cause additional administrative effort. This requirement is included, however, so that the market administrators can ensure that proper payment is made for milk purchased from producers and cooperatives. There is no difference in this requirement other than the accounting for protein, other solids and butterfat in transfers and diversions.

The suggestions by TAPP that the decision contain a larger neutral range and a constant somatic cell adjuster will not be included in this decision. A larger neutral range, particularly around the mean, would provide producers little incentive to reduce herd somatic cell counts below the neutral zone. Depending on the size of the neutral zone, this could be a reduction of 100,000 or more. The somatic cell adjustment provisions adopted in this decision will result in a neutral range of approximately a plus and minus 7,000 somatic cell count from 350,000.

The economic rationale for a somatic cell adjustment is the effect that somatic cells have on protein and the resulting cheese yield. Therefore, it is logical and appropriate to adjust the somatic cell adjustment rate according to changes in the value of cheese. The somatic cell adjustment rate in this decision is moderated in that it does not reflect the value of the entire change in cheese yield that occurs as somatic cell counts in milk change.

The assertion by some exceptors that there is not a straight-line relationship between cheese yield and somatic cell count is not supported by the hearing record. A witness who has done research in such areas testified that on an individual cow basis the relationship is not linear, but that when the milk of multiple cows and farms is intermingled in a bulk tank, the relationship becomes a linear, or straight-line, relationship.

Use of a somatic cell count base point of 350,000 is appropriate, especially because the somatic cell adjustments on the handler and producer sides will be pooled. The 350,000 base point is very close to the average somatic cell count for these markets. The smaller the value of the somatic cell adjustment, the less effect the pooling of somatic cells will have on the producer price differential. Contrary to the exceptions filed by NFO, the effect of the somatic cell adjustment on the average Chicago Regional milk producers was computed to be a plus 3 cents per hundredweight rather than a negative 3 cents.

Concerns were expressed by several of those filing comments that inclusion of a somatic cell adjuster under the orders would reduce current quality premiums prevalent in the marketplace. This decision in no way discourages a handler from paying premiums for quality at whatever rate the handler deems appropriate, as long as producers are paid the minimum Federal order price. In fact, the rate of adjustment for somatic cell count included in the orders is not intended to represent the entire value of the somatic cell effect on milk. In addition, administration of an SCC adjustment under the orders should result in greater handler and producer confidence in the accuracy of the somatic cell counts on which such premium payments are based.

The objection by many of the parties filing exceptions to the somatic cell adjustment that the cost of testing and reporting somatic cell counts would be an excessive burden on producers and their cooperative associations is difficult to understand. According to the record, handlers are already testing widely for somatic cells and adjusting producers' payments on the basis of those tests.

Several parties argued that a somatic cell adjustment should not be included because the Federal milk orders should not be involved in quality issues. However, the Agricultural Marketing Agreement Act in section 8c(5) 7 U.S.C. 608c(5) specifically authorizes adjustments to prices paid to producers for ''the grade or quality of the milk delivered.'' The record of this hearing clearly shows that the presence of somatic cells directly affects the economic value of producer milk.

The somatic cell adjustment provisions adopted herein do not establish standards, such as the Grade A standard under the PMO, but only serve to reflect some of the value to handlers of the level of somatic cells in milk. Although testing for somatic cell counts on a once-per-month basis may be sufficient for the purpose of assuring that a dairy farm is consistently below the maximum allowed level for Grade A status, testing for payment purposes must be done more often. As noted by several exceptors, somatic cell counts are more variable than other characteristics for which milk is commonly tested. More frequent samples and tests are necessary for payment purposes than for the purpose of assuring compliance with health standards to assure that the most accurate possible picture of each producer's production is obtained. The testing monitored by market administrators will cause no conflict with state testing programs because it will not be used to determine compliance with the Grade A standard.

There is no disagreement that somatic cell testing is more variable than butterfat testing. However, the record shows that most producers whose milk is pooled under these orders currently are having adjustments made to their milk checks on the basis of such testing. The hearing record supports the idea that the reliability and accuracy of somatic cell testing are within acceptable tolerances when testing instruments are calibrated correctly. It is expected that these aspects of somatic cell testing will be improved under the supervision of the market administrators for these orders.

The contention that the inclusion of a somatic cell adjuster in these five orders will cause disorderly marketing conditions between these and neighboring orders has no basis. There currently is not, nor ever has been, perfect coordination of pricing between the orders. Even though attempts are made to align prices between orders through location adjustments, other variables such as Class I utilization tend to result in different uniform prices in overlapping procurement areas. The limited magnitude of the somatic cell adjustment will not create any more distortion than already may occur in these marketing areas.

5. *Conforming changes.* To accommodate multiple component pricing a number of changes need to be made in the current order provisions of the five orders in this decision. To

compute a handler's obligation and the producer price differential, several prices need to be defined. The Class I differential price should be defined as the difference between the current month's Class I price and the current month's Class III price. The Class II differential price should be defined as the difference between the current month's Class II price and the current month's Class III price. These differential prices should not be confused with the fixed values that are added to the Minnesota-Wisconsin price for the second preceding month to arrive at the Class I and Class II prices for the current month. The Class III–A differential price should be defined as the difference between the current month's Class III–A price and the current month's Class III price. It should also be pointed out that these differential prices may be negative, which currently happens when the Minnesota-Wisconsin price is greater than any of these prices. The skim milk price will be calculated by subtracting from the Class III price the value determined by multiplying the butterfat differential by 35. The skim milk price will be expressed on a per hundredweight basis with two places to the right of the decimal.

Since producer location adjustments are not changed in this decision, the application of such adjustments to the producer price differential remains unchanged. In some of the orders the uniform price is ''snubbed'' at the Class III price when producer location adjustments are applied. In these orders, the producer price differential will be adjusted for location until the producer price differential is zero if the producer price differential at the zero zone is zero or greater. However, if the producer price differential is negative, no minus producer location adjustment will be applied. Plus adjustments to a negative producer price differential would be made. In those orders in which the uniform price is not ''snubbed'' to the Class III price, producer location adjustments will be applied as they are currently.

For the Market Administrator to compute the producer price differential handlers will need to supply additional information on their monthly reports of receipts and utilization. In addition to the product pounds and butterfat currently reported, handlers will be required to report pounds of protein, pounds of other solids, and somatic cell information. This data will be required from each handler for all producer receipts, including milk diverted by the handler, receipts from cooperatives as 9(c) handlers; and, in some cases, receipts of bulk milk received by transfer or diversion.

The recommended decision proposed that for the Upper Midwest order only, the due date for handlers to submit reports of receipts and utilization be changed from the 10th of the month to the 8th of the month to allow a longer period of time for the processing of data and the announcement of the producer price differential. A number of Upper Midwest handlers filed vehement exceptions to the proposal on the basis that they would need all the time they were accustomed to having to prepare their handler reports and make evaluations with respect to which milk should be pooled or depooled.

As a result of the comments filed by a number of handlers, the reporting date for the Upper Midwest order will remain the 10th. However, as suggested in the comments filed by AMPI North Central Region and Schroeder Milk Company, Inc., the market administrator will be given additional time (1 day, until the 12th) to complete the pooling process and announce the uniform price.

In addition to allowing an additional day for the market administrator to compute the producer price differential, the order is amended to maintain the amount of time currently allowed handlers to make payments into the producer-settlement fund by moving the date by which such payments must be made from the 15th to the 16th of the month. The date for making payments to the administrative and marketing services funds will also be changed from the 15th to the 16th. The date by which the market administrator must make payments from the producer-settlement fund will remain the 17th.

For purposes of allocation of producer receipts the assumption will be made that the protein and other solids cannot easily be separated from skim milk. The protein and other solids will therefore be allocated proportionately with the skim milk based on the percentage of protein and other solids in the skim milk received from producers.

The implementation of this multiple component pricing decision will require several changes in the way handlers pay for milk. Partial payment at the Class III price for the previous month for milk deliveries during the first 15 days of a month was proposed by both NAJ and CMPC. Although no objections to the proposal were expressed, there was no testimony supporting or opposing the proposal. Therefore, there is no basis in the record of the proceeding to make substantive changes in the payment provisions of the orders that provide for partial payments at a significantly different level.

Currently, the Nebraska-Western Iowa order, the Upper Midwest order, and the Iowa order require partial payments to be based on the prior month's uniform price. Since this component pricing plan does not contain a uniform price, these three orders will be changed to require the partial payments to be made at the ''statistical uniform price'', announced by the market administrator on or before the 12th day of the month for which partial payment is to be made.

The Chicago Regional order will also be changed from the current requirement that the partial payment be based on the lowest class price for the prior month to a partial payment based on the prior month's Class III price. The Eastern South Dakota order does not need to be changed.

Final payment to producers will be determined by the total hundredweight of milk times the producer price differential adjusted by the applicable location adjustment, plus or minus the total hundredweight of milk times the adjustment for somatic cells, plus the pounds of protein times the protein price, plus the pounds of other solids times the other solids price, plus the pounds of butterfat times the butterfat price, minus any authorized deductions currently allowed.

Handlers purchasing milk from cooperative pool plants will pay for Class I milk at the Class I differential price plus the pounds of skim milk in Class I at the skim milk price plus the pounds of butterfat at the butterfat price; for Class II and Class III–A milk at the Class II and Class III–A differential prices, respectively, plus the pounds of protein at the protein price, plus the pounds of other solids at the other solids price, plus the pounds of butterfat at the butterfat price; and for Class III milk at the protein pounds times the protein price, plus the pounds of other solids at the other solids price, plus the pounds of butterfat at the butterfat price. The value of milk used in Class II and Class III will be adjusted by the appropriate somatic cell adjustment. Payment for 9(c) milk will be based on the producer price differential adjusted for location at the plant of receipt and somatic cells, plus the value of protein, other solids, and butterfat contained in the milk.

Since producers will be receiving payments based on the component levels of their milk, the payroll reports that handlers supply to producers must reflect the basis for such payment. Therefore the handler will be required to supply the producer not only with the information currently supplied, but

also: (a) The pounds of butterfat, the pounds of protein, and the pounds of other solids contained in the producer's milk, as well as the producer's average somatic cell count, and (b) the minimum rates that are required for payment for each pricing factor and, if a different rate is paid, the effective rate also.

Land O'Lakes, AMPI North Central Region, and Cass-Clay Creamery filed comments excepting to the requirement that handlers report to their producers the pounds and prices of components for which the producers are being paid. LOL and Cass-Clay stated that there is not enough room on producer checks to report such information. AMPI observed that co-ops can reblend returns to producers, and that it would be confusing to producers to see both minimum component rates and possibly reblended rates on the same pay statement.

The requirement that payment factors be reported to producers when producers are paid currently exists in all of these orders. Addition of the component information is purely a conforming change, and should not be changed from the recommended decision. Administration of these provisions should not change from current practices.

The handler's value of milk will be determined by combining: (a) The pounds of producer milk in Class I times the Class I differential price, (b) the pounds of producer milk in Class II times the Class II differential price, (c) the value of overage, (d) the value of inventory reclassification, (e) the value, at the Class I minus Class III price difference, of other source receipts and receipts from unregulated supply plants allocated to Class I, (g) the value of handler location adjustments, (h) Class III–A credits, (i) the pounds of skim milk in Class I times the skim milk price, (j) the pounds of protein in Class II and Class III times the protein price, (k) the pounds of other solids in Class II and Class III times the other solids price, and (l) the somatic cell count of milk used in Classes II and III.

The pounds of protein and other solids in Class II and Class III will be determined by multiplying the percent protein or percent other solids in the skim milk of the total producer milk received by the handler times the pounds of skim milk allocated to Class II and Class III.

Handlers' obligations to the producer settlement fund will be determined by subtracting from the handler's value of milk the following: (a) The total pounds of each handler's producer milk times the producer price differential adjusted for location, (b) the total pounds of protein contained in the producer milk times the protein price, (c) the total pounds of other solids contained in the producer milk times the other solids price, (d) the total value of somatic cell adjustments to the handler's producer milk, and (e) the value of other source milk at the producer price differential with any applicable location adjustment at the plant from which the milk was shipped deducted from the handler's value of milk.

The amendments to order language accompanying this decision are based on the current language of the five orders, which include any changes to the orders made necessary by the two national amendatory proceedings (Class II pricing and the M–W replacement) that were completed in March and April 1995.

A number of the handlers who filed comments on the recommended decision expressed a desire for additional time between approval of the final decision and the effective date of the amendments to allow the industry affected by the order amendments to make a more orderly transition to the new payment system and conduct the necessary informational meetings. They expressed a need for caution and gradualism in effecting the proposed ''revolutionary'' changes in the historic method of pricing milk.

The request for additional time to implement the changes that will be necessary in computer programs, administrative systems and laboratory arrangements is reasonable, and should be accommodated. Accordingly, there will be a longer-than-usual interval between approval of the orders as amended and the effective date of the final order.

Rulings on Proposed Findings and Conclusions

Briefs and proposed findings and conclusions were filed on behalf of certain interested parties. These briefs, proposed findings and conclusions and the evidence in the record were considered in making the findings and conclusions set forth above. To the extent that the suggested findings and conclusions filed by interested parties are inconsistent with the findings and conclusions set forth herein, the requests to make such findings or reach such conclusions are denied for the reasons previously stated in this decision.

General Findings

The findings and determinations hereinafter set forth supplement those that were made when the Chicago Regional and certain other orders were first issued and when they were amended. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth herein.

(a) The tentative marketing agreements and the orders, as hereby proposed to be amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(b) The parity prices of milk as determined pursuant to section 2 of the Act are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the marketing area, and the minimum prices specified in the tentative marketing agreements and the orders, as hereby proposed to be amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(c) The tentative marketing agreements and the orders, as hereby proposed to be amended, will regulate the handling of milk in the same manner as, and will be applicable only to persons in the respective classes of industrial and commercial activity specified in, marketing agreements upon which a hearing has been held.

Rulings on Exceptions

In arriving at the findings and conclusions, and the regulatory provisions of this decision, each of the exceptions received was carefully and fully considered in conjunction with the record evidence. To the extent that the findings and conclusions and the regulatory provisions of this decision are at variance with any of the exceptions, such exceptions are hereby overruled for the reasons previously stated in this decision.

Marketing Agreement and Order

Annexed hereto and made a part hereof are two documents, a Marketing Agreement regulating the handling of milk, and an Order amending the orders regulating the handling of milk in the Chicago Regional and certain other marketing areas, which have been decided upon as the detailed and appropriate means of effectuating the foregoing conclusions.

It is hereby ordered that this entire decision and the two documents annexed hereto be published in the **Federal Register**.

Determination of Producer Approval and Representative Period

December 1994 is hereby determined to be the representative period for the purpose of ascertaining whether the issuance of the orders, as amended and as hereby proposed to be amended, regulating the handling of milk in the Chicago Regional and certain other marketing areas is approved or favored by producers, as defined under the terms of the orders (as amended and as hereby proposed to be amended), who during such representative period were engaged in the production of milk for sale within the aforesaid marketing areas.

List of Subjects in 7 CFR Parts 1030, 1065, 1068, 1076 and 1079

Milk marketing orders.

Dated: August 3, 1995.

Patricia Jensen,

Acting Assistant Secretary, Marketing and Regulatory Programs.

Order Amending the Orders Regulating the Handling of Milk in the Chicago Regional and Certain Other Marketing Areas

(This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.)

Findings and Determinations

The findings and determinations hereinafter set forth supplement those that were made when the orders were first issued and when they were amended. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth herein.

(a) Findings. A public hearing was held upon certain proposed amendments to the tentative marketing agreement and to the orders regulating the handling of milk in the Chicago Regional and certain other marketing areas. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and the applicable rules of practice and procedure (7 CFR part 900).

Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said orders as hereby amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(2) The parity prices of milk, as determined pursuant to section 2 of the Act, are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the aforesaid marketing areas. The minimum prices specified in the orders as hereby amended are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(3) The said orders as hereby amended regulate the handling of milk in the same manner as, and is applicable only to persons in the respective classes of industrial or commercial activity specified in, marketing agreements upon which a hearing has been held.

Order Relative to Handling

It is therefore ordered, that on and after the effective date hereof, the handling of milk in the Chicago Regional and certain other marketing areas shall be in conformity to and in compliance with the terms and conditions of the order, as amended, and as hereby amended, as follows:

The provisions of the proposed marketing agreement and order amending the orders contained in the recommended decision issued by the Administrator, Agricultural Marketing Service, on October 25, 1994, and published in the **Federal Register** on November 2, 1994 (59 FR 54952), shall be and are the terms and provisions of this order, amending the orders, and are set forth in full herein, subject to the following modifications:

a. Changes in the treatment of somatic cell adjustments require modifications of reporting requirements in § 1030.30(a)(1) and the corresponding sections of the other 4 orders.

b. Additional changes due to the treatment of the somatic cell adjustment have been made in §§ 1030.50(l), 1030.53(i), 1030.60(a)(6), 1030.61(a)(2), 1030.62(e), 1030.71(a)(2)(iv), 1030.73(c)(2)(vi), and the corresponding sections of the other 4 orders.

c. Changes in the computation of the Other Solids Price have been made in § 1030.50(k), and in the corresponding sections of the other 4 orders.

d. Changes for the purpose of more easily accommodating Class III–A provisions have been made by adding §§ 1030.50(g) and 1030.60(a)(7), deleting 1030.61(a)(3), and making the same changes in the other 3 orders that have Class III–A provisions.

e. Changes for the purpose of conforming with changes to the orders resulting from the Class II pricing proceeding have been made in §§ 1030.53(b) and the corresponding sections of the other 4 orders.

f. Changes for the purpose of conforming with changes to the orders resulting from the M–W replacement proceeding have been made in § 1030.74 and the corresponding sections of the other 4 orders.

g. Changes for the purpose of clarifying the amended order have been made in §§ 1030.71(a)(2)(v) and 1030.75(b) and the corresponding sections of those orders for which such changes are appropriate.

h. Changes in the Upper Midwest reporting date, the date for announcing the producer price differential and the date by which payments must be made to the producer-settlement fund have been made in §§ 1068.30, 1068.62, 1068.71(a), 1068.85 and 1068.86.

Accordingly, this decision proposes 7 CFR chapter X be amended as follows:

1. The authority citation for 7 CFR parts 1030, 1065, 1068, 1076 and 1079 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

PART 1030—MILK IN THE CHICAGO REGIONAL MARKETING AREA

1. Section 1030.30 is amended by revising paragraphs (a) and (c) and removing paragraph (d), to read as follows:

§ 1030.30 Reports of receipts and utilization.

* * * * *

(a) Each handler described in § 1030.9(a) shall report for each plant of the handler (except if a handler requests and the request is approved by the market administrator, a handler may file a consolidated report for supply plants and a consolidated report for distributing plants); and each handler described in § 1030.9(b) and (c) shall report the following information:

(1) Product pounds, pounds of butterfat, pounds of protein, pounds of solids-not-fat other than protein (other solids), and the value of the somatic cell adjustment contained in or represented by:

(i) Receipts of producer milk, including producer milk diverted by the handler from the pool plant to other plants; and

(ii) Receipts of milk from handlers described in § 1030.9(c).

(2) Product pounds and pounds of butterfat contained in:

(i) Receipts by transfer or diversion of bulk fluid milk products from pool plants, including a separate statement of the net receipts from each supply plant computed pursuant to § 1030.7(b)(4);

(ii) Receipts of fluid milk products not included in paragraph (a)(1) or (a)(2)(i)

of this section and bulk fluid cream products from any source;

(iii) Receipts of other source milk; and

(iv) Inventories at the beginning and end of the month of fluid milk products and products specified in § 1030.40(b)(1).

(3) The utilization or disposition of all milk, filled milk, and milk products required to be reported pursuant to this paragraph.

(4) Such other information with respect to the receipts and utilization of skim milk, butterfat, milk protein, other nonfat solids, and somatic cell information, as the market administrator may prescribe.

* * * * *

(c) Each handler not specified in paragraphs (a) and (b) of this section shall report with respect to its receipts and utilization of milk, filled milk, and milk products in such manner as the market administrator may prescribe.

2. Section 1030.31 is amended by revising paragraph (a) to read as follows:

§ 1030.31 Payroll reports.

(a) On or before the 25th day after the end of each month, each handler described in § 1030.9(a), (b), and (c) shall report to the market administrator its producer payroll for such month, in the detail prescribed by the market administrator, showing for each producer the information specified in § 1030.73(e).

* * * * *

3. Section 1030.50 is amended by revising the section heading, introductory text and paragraph (a), and adding paragraphs (e) through (l) to read as follows:

§ 1030.50 Class and component prices.

Subject to the provisions of § 1030.52, the class prices per hundredweight of milk containing 3.5 percent butterfat and the component prices for the month shall be as follows:

(a) *Class I price.* The Class I price for the month per hundredweight of milk containing 3.5 percent butterfat shall be the basic formula price for the second preceding month plus $1.40.

* * * * *

(e) *Class I differential price.* The Class I differential price shall be the difference between the current month's Class I and Class III prices (this price may be negative).

(f) *Class II differential price.* The Class II differential price shall be the difference between the current month's Class II and Class III prices (this price may be negative).

(g) *Class III–A differential price.* The Class III–A differential price shall be the difference between the current month's Class III and Class III–A prices (this price may be negative).

(h) *Skim milk price.* The skim milk price per hundredweight, rounded to the nearest cent, shall be the Class III price less an amount computed by multiplying the butterfat differential by 35.

(i) *Butterfat price.* The butterfat price per pound, rounded to the nearest one-hundredth cent, shall be the Class III price plus an amount computed by multiplying the butterfat differential by 965 and dividing the resulting amount by one hundred.

(j) *Protein price.* The protein price per pound, rounded to the nearest one-hundredth cent, shall be 1.32 times the average monthly price per pound for 40-pound block Cheddar cheese on the National Cheese Exchange as reported by the Department.

(k) *Other solids price.* Other solids are herein defined as solids-not-fat other than protein. The other solids price per pound, rounded to the nearest one-hundredth cent, shall be the basic formula price at test less the average butterfat test of the basic formula price as reported by the Department times the butterfat price, less the average protein test of the basic formula price as reported by the Department for the month times the protein price, and dividing the resulting amount by the average other solids test of the basic formula price as reported by the Department. If the resulting price is less than zero, then the protein price will be reduced so that the other solids price equals zero.

(l) *Somatic cell adjustment.* (1) The somatic cell adjustment rate per 1,000 somatic cells, rounded to five decimal places, shall be computed by multiplying .0005 times the monthly cheddar cheese price as defined in paragraph (j) of this section.

(2) The somatic cell adjustment, per hundredweight, shall be determined by subtracting from 350 the somatic cell count (in thousands) of the milk, multiplying the difference by the somatic cell adjustment rate, and rounding to the nearest full cent.

4. Section 1030.53, including the section heading, is revised to read as follows:

§ 1030.53 Announcement of class and component prices.

On or before the 5th day of the month, the market administrator shall announce the following prices:

(a) The Class I price for the following month;

(b) The Class II price for the following month;

(c) The Class III price for the preceding month;

(d) The Class III–A price for the preceding month;

(e) The skim milk price for the preceding month;

(f) The butterfat price for the preceding month;

(g) The protein price for the preceding month;

(h) The other solids price for the preceding month;

(i) The somatic cell adjustment rate for the preceding month; and

(j) The butterfat differential for the preceding month.

5. The section heading in § 1030.60 and the undesignated centerheading preceding it, the introductory text, and paragraphs (a) and (f) are revised to read as follows:

Producer Price Differential

§ 1030.60 Handler's value of milk.

For the purpose of computing a handler's obligation for producer milk, the market administrator shall determine for each month the value of milk of each handler described in § 1030.9(a), (b), and (c), as follows:

(a) Calculate the following values:

(1) Multiply the total hundredweight of producer milk in Class I as determined pursuant to § 1030.44(c) by the Class I differential price for the month;

(2) Add an amount obtained by multiplying the total hundredweight of producer milk in Class II as determined pursuant to § 1030.44(c) by the Class II differential price for the month;

(3) Add an amount obtained by multiplying the hundredweight of skim milk in Class I as determined pursuant to § 1030.44(a) by the skim milk price;

(4) Add an amount obtained by multiplying the pounds of skim milk in Class II and Class III as determined pursuant to § 1030.44(a) by the average protein content of producer skim milk received by the handler, and multiplying the resulting pounds of protein by the protein price;

(5) Add an amount obtained by multiplying the pounds of skim milk in Class II and Class III as determined pursuant to § 1030.44(a) by the average other solids content of producer skim milk received by the handler, and multiplying the resulting pounds of other solids by the other solids price;

(6) Add an adjustment for somatic cell content determined by multiplying the value reported pursuant to § 1030.30(a)(1) by the percentage of the total producer milk allocated pursuant to § 1030.44(c) that is allocated to Class II and Class III; and

(7) Add an amount obtained by multiplying the total hundredweight of producer milk eligible to be priced as Class III–A by the Class III–A differential price for the month.

* * * * *

(f) Add the amount obtained from multiplying the Class I differential price applicable at the location of the nearest unregulated supply plants from which an equivalent volume was received by the pounds of skim milk and butterfat in receipts of concentrated fluid milk products assigned to Class I pursuant to § 1030.43(d) and § 1030.44(a)(7)(i) and the pounds of skim milk and butterfat subtracted from Class I pursuant to § 1030.44(a)(11) and the corresponding steps of § 1030.44(b), excluding such skim milk and butterfat in receipts of bulk fluid milk products from an unregulated supply plant to the extent that an equivalent amount of skim milk or butterfat disposed of to such plant by handlers fully regulated under any Federal milk order is classified and priced as Class I milk and is not used as an offset for any other payment obligation under any order;

* * * * *

6. Section 1030.61 is amended by revising the section heading, introductory text, and paragraph (a) to read as follows:

§ 1030.61 Producer price differential.

For each month the market administrator shall compute a producer price differential per hundredweight for Zone 1. If the unreserved cash balance in the producer settlement fund to be included in the computation is less than 2 cents per hundredweight of producer milk on all reports, the report of any handler who has not made the payments required pursuant to § 1030.71 for the preceding month shall not be included in the computation of the producer price differential. The report of such handler shall not be included in the computation for succeeding months until the handler has made full payment of outstanding monthly obligations. Subject to the aforementioned conditions, the market administrator shall compute the producer price differential in the following manner:

(a) Combine into one total for all handlers:

(1) The values computed pursuant to § 1030.60(a)(1), (a)(2), (a)(7), and (b) through (k) for all handlers; and

(2) Add values computed pursuant to § 1030.60(a)(3), (a)(4), (a)(5) and (a)(6); and subtract the values obtained by multiplying the handlers' total pounds of protein and total pounds of other solids contained in such milk by their respective prices, and the total value of the somatic cell adjustment.

* * * * *

7. **Section 1030.62 is revised to read as follows:**

§ 1030.62 Announcement of producer prices.

On or before the 14th day after the end of each month, the market administrator shall announce the following prices and information:

(a) The producer price differential;

(b) The protein price;

(c) The other solids price;

(d) The butterfat price;

(e) The somatic cell adjustment rate:

(f) The average butterfat, protein and other solids content of producer milk; and

(g) The statistical uniform price for milk containing 3.5 percent butterfat, computed by combining the Class III price and the producer price differential.

8. Section 1030.71 is amended by revising paragraph (a)(2) to read as follows:

§ 1030.71 Payments to the producer-settlement fund.

(a) * * *

(2) The sum of:

(i) An amount obtained by multiplying the total hundredweight of producer milk as determined pursuant to § 1030.44(c) by the producer price differential as adjusted pursuant to § 1030.75;

(ii) An amount obtained by multiplying the total pounds of protein contained in producer milk by the protein price;

(iii) An amount obtained by multiplying the total pounds of other solids contained in producer milk by the other solids price;

(iv) The total value of the somatic cell adjustment to producer milk; and

(v) An amount obtained by multiplying the pounds of skim milk and butterfat for which a value was computed pursuant to § 1030.60(f) by the producer price differential as adjusted pursuant to § 1030.52 for the location of the plant from which received.

* * * * *

9. Section 1030.73 is amended by revising paragraphs (a), (c), and (d) and adding a new paragraph (e), to read as follows:

§ 1030.73 Payments to producers and to cooperative associations.

(a) Each handler shall pay each producer for producer milk received from such producer and for which payment is not made to a cooperative association pursuant to paragraph (b) or (c) of this section as follows:

(1) On or before the 3rd day after the end of each month, to each producer who has not discontinued shipping milk to such handler before the end of the month, for producer milk received during the first 15 days of the month at a rate per hundredweight not less than the Class III price for milk of 3.5 percent butterfat for the preceding month, less proper deductions authorized in writing by such producer; and

(2) On or before the 18th day after the end of the month, payment for producer milk received during such month shall not be less than the sum of:

(i) The hundredweight of producer milk received times the producer price differential as adjusted pursuant to §§ 1030.75 and 1030.86;

(ii) The pounds of butterfat received times the butterfat price for the month;

(iii) The pounds of protein received times the protein price for the month;

(iv) The pounds of other solids received times the other solids price for the month;

(v) The hundredweight of milk received times the somatic cell adjustment for the month;

(vi) Less any payment made pursuant to paragraph (a) of this section;

(vii) Less proper deductions authorized in writing by such producer and plus or minus adjustments for errors in previous payments made to such producer; and

(3) If by such date the handler has not received full payment from the market administrator pursuant to § 1030.72 for such month, it may reduce pro rata its payment to producers by not more than the amount of such underpayment. Payment to producers shall be completed thereafter not later than the date for making payments pursuant to this paragraph next following receipt of the balance due from the market administrator.

* * * * *

(c) Each handler shall pay a cooperative association for milk received by the handler from pool plant(s) operated by a cooperative association as follows:

(1) For milk received during the first 15 days of the month, the handler shall pay the cooperative association on or before the 1st day after the end of the month during which the milk was received at a rate per hundredweight not less than the Class III price for milk of 3.5 percent butterfat for the preceding month; and

(2) For milk received and classified during the month the handler shall pay the cooperative association on or before

the 16th day after the end of the month during which the milk was received as follows:

(i) The hundredweight of Class I milk received times the Class I differential price for the month plus the pounds of Class I skim milk times the skim milk price for the month;

(ii) The hundredweight of Class II milk received times the Class II differential price for the month;

(iii) The hundredweight of Class III–A milk received times the Class III–A differential price for the month;

(iv) The pounds of butterfat received times the butterfat price for the month;

(v) The pounds of protein received in Class II and Class III milk times the protein price for the month;

(vi) The pounds of other solids received in Class II and Class III milk times the other solids price for the month;

(vii) The hundredweight of Class II and Class III milk received times the somatic cell adjustment; and

(viii) Less any payment made pursuant to paragraph (c)(1) of this section.

(d) Each handler shall pay a cooperative association for milk received by the handler from a cooperative association acting as a handler described under § 1030.9(c) as follows:

(1) For milk received during the first 15 days of the month, the handler shall pay the cooperative association on or before the 1st day after the end of the month during which the milk was received at a rate per hundredweight not less than the Class III price for milk of 3.5 percent butterfat for the preceding month; and

(2) For milk received during the month the handler shall pay the cooperative association on or before the 16th day after the end of the month during which the milk was received as follows:

(i) The hundredweight of milk received times the producer price differential as adjusted pursuant to § 1030.75;

(ii) The pounds of butterfat received times the butterfat price for the month;

(iii) The pounds of protein received times the protein price for the month;

(iv) The pounds of other solids received times the other solids price for the month;

(v) The hundredweight of milk received times the somatic cell adjustment for the month;

(vi) Less any payment made pursuant to paragraph (d)(1) of this section;

(vii) Less proper authorized deductions.

(e) In making payments for producer milk pursuant to paragraphs (a)(2) or (b)(2) of this section, each handler shall furnish each producer or cooperative association to whom such payment is made a supporting statement in such form that it may be retained by the recipient which shall show:

(1) The month and the identity of the producer;

(2) The daily and total pounds for each producer;

(3) The total pounds of butterfat contained in the producer's milk;

(4) The total pounds of protein contained in the producer's milk;

(5) The total pounds of other solids contained in the producer's milk;

(6) The somatic cell count of the producer's milk;

(7) The minimum rate or rates at which payment to the producer is required pursuant to this order;

(8) The rate that is used in making payment if such rate is other than the applicable minimum rate;

(9) The amount, or the rate per hundredweight, or rate per pound of component, and the nature of each deduction claimed by the handler; and

(10) The net amount of payment to such producer or cooperative.

10. Sections 1030.74 and 1030.75 are revised to read as follows:

§ 1030.74 Butterfat differential.

The butterfat differential, rounded to the nearest one-tenth cent, shall be 0.138 times the current month's butter price less 0.0028 times the preceding month's average pay price per hundredweight, at test, for manufacturing grade milk in Minnesota and Wisconsin, using the ''base month'' series, adjusted pursuant to § 1030.51 (a) through (e), as reported by the Department. The butter price means the simple average for the month of the Chicago Mercantile Exchange Grade A butter price as reported by the Department.

§ 1030.75 Plant location adjustments for producers and on nonpool milk.

(a) The producer price differential for producer milk received at a plant shall be adjusted according to the location of the plant at the rates set forth in § 1030.52(a).

(b) The producer price differential applicable to other source milk shall be adjusted at the rates set forth in § 1030.52(a), except that the adjusted producer differential price shall not be less than zero.

11. Section 1030.76 is amended by revising paragraph (a)(4) and the third sentence of paragraph (b)(1)(ii) to read as follows, and changing the reference ''§ 1030.71(a)(2)(ii)'' in paragraph (b)(1)(iii) to ''§ 1030.71(a)(2)(v)'':

§ 1030.76 Payments by handler operating a partially regulated distributing plant.

* * * * *

(a) * * *

(4) Multiply the remaining pounds by the amount by which the Class I differential price exceeds the producer price differential, both prices to be applicable at the location of the partially regulated distributing plant; and

* * * * *

(b) * * *

(1) * * *

(ii) * * * Any such transfers remaining after the above allocation which are classified in Class I and for which a value is computed for the handler operating the partially regulated distributing plant pursuant to § 1030.60 shall be priced at the statistical uniform price (or at the weighted average price if such is provided) of the respective order regulating the handling of milk at the transferee-plant, with such statistical uniform price adjusted to the location of the nonpool plant (but not to be less than the lowest class price of the respective order), except that transfers of reconstituted skim milk in filled milk shall be priced at the lowest class price of the respective order; and

* * * * *

PART 1065—MILK IN THE NEBRASKA-WESTERN IOWA MARKETING AREA

1. Section 1065.30 is amended by revising paragraphs (a) and (c) and removing paragraph (d), to read as follows:

§ 1065.30 Reports of receipts and utilization.

* * * * *

(a) Each handler described in § 1065.9(a), (b), and (c) shall report for each of its operations the following information:

(1) Product pounds, pounds of butterfat, pounds of protein, pounds of solids-not-fat other than protein (other solids), and the value of the somatic cell adjustment contained in or represented by:

(i) Receipts of producer milk, including producer milk diverted by the handler; and

(ii) Receipts of milk from handlers described in § 1065.9(c).

(2) Product pounds and pounds of butterfat contained in:

(i) Receipts by transfer or diversion of bulk fluid milk products from pool plants;

(ii) Receipts of fluid milk products not included in paragraph (a)(1) or (a)(2)(i) of this section and bulk fluid cream products from any source;

(iii) Receipts of other source milk; and

(iv) Inventories at the beginning and end of the month of fluid milk products and products specified in § 1065.40(b)(1).

(3) The utilization or disposition of all milk, filled milk, and milk products required to be reported pursuant to this paragraph.

(4) Such other information with respect to the receipts and utilization of skim milk, butterfat, milk protein, other nonfat solids, and somatic cell information, as the market administrator may prescribe.

* * * * *

(c) Each handler not specified in paragraphs (a) and (b) of this section shall report with respect to its receipts and utilization of milk, filled milk, and milk products in such manner as the market administrator may prescribe.

2. Section 1065.31 is amended by revising paragraph (a) to read as follows:

§ 1065.31 Payroll reports.

(a) On or before the 20th day after the end of each month, each handler described in § 1065.9(a), (b), and (c) shall report to the market administrator its producer payroll for such month, in the detail prescribed by the market administrator, showing for each producer the information described in § 1065.73(e).

* * * * *

3. Section 1065.50 is amended by revising the section heading, introductory text and paragraph (a), and adding paragraphs (e) through (l), to read as follows:

§ 1065.50 Class and component prices.

Subject to the provisions of § 1065.52, the class prices per hundredweight of milk containing 3.5 percent butterfat and the component prices for the month shall be as follows:

(a) *Class I price.* The Class I price for the month per hundredweight of milk containing 3.5 percent butterfat shall be the basic formula price for the second preceding month plus $1.75.

* * * * *

(e) *Class I differential price.* The Class I differential price shall be the difference between the current month's Class I and Class III prices (this price may be negative).

(f) *Class II differential price.* The Class II differential price shall be the difference between the current month's Class II and Class III prices (this price may be negative).

(g) *Class III–A differential price.* The Class III–A differential price shall be the difference between the current month's Class III and Class III–A prices (this price may be negative).

(h) *Skim milk price.* The skim milk price per hundredweight, rounded to the nearest cent, shall be the Class III price less an amount computed by multiplying the butterfat differential by 35.

(i) *Butterfat price.* The butterfat price per pound, rounded to the nearest one-hundredth cent, shall be the Class III price plus an amount computed by multiplying the butterfat differential by 965 and dividing the resulting amount by one hundred.

(j) *Protein price.* The protein price per pound, rounded to the nearest one-hundredth cent, shall be 1.32 times the average monthly price per pound for 40-pound block Cheddar cheese on the National Cheese Exchange as reported by the Department.

(k) *Other solids price.* Other solids are herein defined as solids not fat other than protein. The other solids price per pound, rounded to the nearest one-hundredth cent, shall be the basic formula price at test less the average butterfat test of the basic formula price as reported by the Department times the butterfat price, less the average protein test of the basic formula price as reported by the Department for the month times the protein price, and dividing the resulting amount by the average other solids test of the basic formula price as reported by the Department. If the resulting price is less than zero, then the protein price will be reduced so that the other solids price equals zero.

(l) *Somatic cell adjustment.* (1) The somatic cell adjustment rate, per 1,000 somatic cells, rounded to five decimal places, shall be computed by multiplying .0005 times the monthly cheddar cheese price as defined in paragraph (j) of this section.

(2) The somatic cell adjustment, per hundredweight, shall be determined by subtracting from 350 the somatic cell count (in thousands) of the milk, multiplying the difference by the somatic cell adjustment rate, and rounding to the nearest full cent.

4. Section 1065.53, including the section heading, is revised to read as follows:

§ 1065.53 Announcement of class and component prices.

On or before the 5th day of the month, the market administrator shall announce the following prices:

(a) The Class I price for the following month;

(b) The Class II price for the following month;

(c) The Class III price for the preceding month;

(d) The Class III–A price for the preceding month;

(e) The skim milk price for the preceding month;

(f) The butterfat price for the preceding month;

(g) The protein price for the preceding month;

(h) The other solids price for the preceding month;

(i) The somatic cell adjustment rate for the preceding month; and

(j) The butterfat differential for the preceding month.

5. The section heading in § 1065.60 and the undesignated centerheading preceding it, the introductory text, and paragraphs (a) and (f) are revised to read as follows:

Producer Price Differential

§ 1065.60 Handler's value of milk.

For the purpose of computing a handler's obligation for milk the market administrator shall determine for each month the value of milk of each handler described in § 1065.9(a) with respect to each of its pool plants and each handler described in § 1065.9(b) and (c).

(a) The handler's obligation for producer milk shall be computed as follows:

(1) Multiply the total hundredweight of milk in Class I as determined pursuant to § 1065.44(c) by the Class I differential price for the month;

(2) Add an amount obtained by multiplying the total hundredweight of milk in Class II as determined pursuant to § 1065.44(c) by the Class II differential price for the month;

(3) Add an amount obtained by multiplying the hundredweight of skim milk in Class I as determined pursuant to § 1065.44(a) by the skim milk price;

(4) Add an amount obtained by multiplying the pounds of skim milk in Class II and Class III as determined pursuant to § 1065.44(a) by the average protein content of producer skim milk received by the handler, and multiplying the resulting pounds of protein by the protein price;

(5) Add an amount obtained by multiplying the pounds of skim milk in Class II and Class III as determined pursuant to § 1065.44(a) by the average other solids content of producer skim milk received by the handler, and multiplying the resulting pounds of other solids by the other solids price.

(6) Add an adjustment for somatic cell content determined by multiplying the value reported pursuant to § 1065.30(a)(1) by the percentage of the total producer milk allocated pursuant to § 1065.44(c) that is allocated to Class II and Class III; and

(7) Add an amount obtained by multiplying the total hundredweight of producer milk eligible to be priced as Class III-A by the Class III-A differential price for the month.

* * * * *

(f) Add the amount obtained from multiplying the Class I differential price applicable at the location of the nearest unregulated supply plants from which an equivalent volume was received by the pounds of skim milk and butterfat in receipts of concentrated fluid milk products assigned to Class I pursuant to § 1065.43(d) and § 1065.44(a)(7)(i) and the pounds of skim milk and butterfat subtracted from Class I pursuant to § 1065.44(a)(11) and the corresponding steps of § 1065.44(b), excluding such skim milk and butterfat in receipts of bulk fluid milk products from an unregulated supply plant to the extent that an equivalent amount of skim milk or butterfat disposed of to such plant by handlers fully regulated under any Federal milk order is classified and priced as Class I milk and is not used as an offset for any other payment obligation under any order;

* * * * *

6. Section 1065.61 is amended by revising the section heading, introductory text, and paragraphs (a) and (f), to read as follows:

§ 1065.61 Producer price differential.

For each month the market administrator shall compute a producer price differential per hundredweight of milk received from producers, as follows:

(a) Combine into one total for all handlers:

(1) The values computed pursuant to § 1065.60(a)(1), (a)(2), (a)(7) and (b) through (i) for all handlers; and

(2) Add values computed pursuant to § 1065.60(a)(3), (a)(4), (a)(5) and (a)(6); and subtract the values obtained by multiplying the handlers' total pounds of protein and total pounds of other solids contained in such milk by their respective prices, and the total value of the somatic cell adjustment.

* * * * *

(f) Subtract not less than 4 cents nor more than 5 cents from the price computed pursuant to paragraph (e) of this section. The result shall be the ''producer price differential.''

7. Section 1065.62 is revised to read as follows:

§ 1065.62 Announcement of producer prices.

On or before the 12th day after the end of each month, the market administrator shall announce the following prices and information:

(a) The producer price differential;

(b) The protein price;

(c) The other solids price;

(d) The butterfat price;

(e) The somatic cell adjustment rate;

(f) The average butterfat, protein and other solids content of producer milk; and

(g) The statistical uniform price for milk containing 3.5 percent butterfat, computed by combining the Class III price and the producer price differential.

8. Section 1065.71 is amended by revising paragraph (a)(2) to read as follows:

§ 1065.71 Payments to the producer-settlement fund.

(a) * * *

(2) The sum of:

(i) An amount obtained by multiplying the total hundredweight of producer milk determined pursuant to § 1065.44(c) by the producer price differential as adjusted pursuant to § 1065.75;

(ii) An amount obtained by multiplying the total pounds of protein contained in producer milk by the protein price;

(iii) An amount obtained by multiplying the total pounds of other solids contained in producer milk by the other solids price;

(iv) The total value of the somatic cell adjustment to producer milk; and

(v) An amount obtained by multiplying the pounds of skim milk and butterfat for which a value was computed pursuant to § 1065.60(f) by the producer price differential as adjusted pursuant to § 1065.52 for the location of the plant from which received.

* * * * *

9. Section 1065.73 is amended by revising paragraphs (a), (c), (d) and (e) to read as follows:

§ 1065.73 Payments to producers and to cooperative associations.

(a) Each handler shall pay for milk received from producers for which payment is not made to a cooperative association pursuant to paragraph (b) or (c) of this section as follows:

(1) On or before the 27th day of the month, to each producer who has not discontinued shipping milk to such handler before the end of the month, for producer milk received during the first 15 days of the month at a rate per hundredweight not less than the statistical uniform price computed pursuant to § 1065.62(g) for the preceding month, less proper deductions authorized in writing by such producer; and

(2) On or before the 18th day after the end of the month, payment for producer milk received during such month shall not be less than the sum of:

(i) The hundredweight of producer milk received times the producer price differential as adjusted pursuant to § 1065.75;

(ii) The pounds of butterfat received times the butterfat price for the month;

(iii) The pounds of protein received times the protein price for the month;

(iv) The pounds of other solids received times the other solids price for the month;

(v) The hundredweight of milk received times the somatic cell adjustment for the month;

(vi) Less any payment made pursuant to paragraph (a)(1) of this section;

(vii) Less proper deductions authorized in writing by such producer and plus or minus adjustments for errors in previous payments made to such producer;

(viii) Less deductions for marketing services pursuant to 1065.86 and for advertising and promotion pursuant to § 1065.107; and

(ix) If by such date the handler has not received full payment from the market administrator pursuant to § 1065.72 for such month, it may reduce pro rata its payment to producers by not more than the amount of such underpayment. Payment to producers shall be completed thereafter not later than the date for making payments pursuant to this paragraph next following receipt of the balance due from the market administrator.

* * * * *

(c) Each handler shall pay a cooperative association for milk received by the handler from a cooperative association acting as a handler described in § 1065.9(c) as follows:

(1) For milk received during the first 15 days of the month, the handler shall pay the cooperative association on or before the 26th day of the month during which the milk was received at a rate per hundredweight not less than the statistical uniform price computed pursuant to § 1065.62(g) for the preceding month; and

(2) For milk received during the month the handler shall pay the cooperative association on or before the 17th day after the end of the month during which the milk was received as follows:

(i) The hundredweight of milk received times the producer price differential applicable at the location of the receiving handler's plant;

(ii) The pounds of butterfat received times the butterfat price for the month;

(iii) The pounds of protein received times the protein price for the month;

(iv) The pounds of other solids received times the other solids price for the month;

(v) The hundredweight of milk received times the somatic cell adjustment for the month; and

(vi) Less any payment made pursuant to paragraph (c)(1) of this section.

(d) Each handler shall pay a cooperative association for fluid milk products received by transfer or diversion from a pool plant operated by the cooperative association as follows:

(1) For milk received during the first 15 days of the month, the handler shall pay the cooperative association on or before the 26th day of the month during which the milk was received at a rate per hundredweight not less than the Class III price for the preceding month; and

(2) For milk received and classified during the month the handler shall pay the cooperative association on or before the 17th day after the end of the month during which the milk was received as follows:

(i) The hundredweight of Class I milk received times the Class I differential price for the month applicable at the transferee plant, plus the pounds of Class I skim milk times the skim milk price for the month;

(ii) The hundredweight of Class II milk received times the Class II differential price for the month;

(iii) The hundredweight of Class III–A milk received times the Class III–A differential price for the month;

(iv) The pounds of butterfat received times the butterfat price for the month;

(v) The pounds of protein received in Class II and Class III milk times the protein price for the month;

(vi) The pounds of other solids received in Class II and Class III milk times the other solids price for the month;

(vii) The hundredweight of Class II and Class III milk received times the somatic cell adjustment; and

(viii) Less any payment made pursuant to paragraph (d)(1) of this section.

(e) In making payments for producer milk pursuant to paragraphs (a)(2) or (b)(2) of this section, each handler shall furnish each producer or cooperative association to whom such payment is made a supporting statement in such form that it may be retained by the recipient which shall show:

(1) The month and the identity of the producer;

(2) The daily and total pounds for each producer;

(3) The total pounds of butterfat contained in the producer's milk;

(4) The total pounds of protein contained in the producer's milk;

(5) The total pounds of other solids contained in the producer's milk;

(6) The somatic cell count of the producer's milk;

(7) The minimum rate or rates which payment to the producer is required pursuant to this order;

(8) The rate that is used in making payment if such rate is other than the applicable minimum rate;

(9) The amount, or the rate per hundredweight, or rate per pound of component, and the nature of each deduction claimed by the handler; and

(10) The net amount of payment to such producer or cooperative.

* * * * *

10. Sections 1065.74 and 1065.75 are revised to read as follows:

§ 1065.74 Butterfat differential.

The butterfat differential, rounded to the nearest one-tenth cent, shall be 0.138 times the current month's butter price less 0.0028 times the preceding month's average pay price per hundredweight, at test, for manufacturing grade milk in Minnesota and Wisconsin, using the ''base month'' series, adjusted pursuant to § 1065.51 (a) through (e), as reported by the Department. The butter price means the simple average for the month of the Chicago Mercantile Exchange Grade A butter price as reported by the Department.

§ 1065.75 Plant location adjustments for producers and on nonpool milk.

(a) The producer price differential for producer milk shall be adjusted according to the location of the plant of actual receipt at the rates set forth in § 1065.52.

(b) For purposes of computations pursuant to §§ 1065.71 and 1065.72, the producer price differential shall be adjusted at the rates set forth in § 1065.52 applicable at the location of the nonpool plant from which the milk was received, except that the adjusted producer price differential shall not be less than zero.

11. Section 1065.76 is amended by revising paragraph (a)(4) and the third sentence of paragraph (b)(1)(ii) to read as follows, and changing the reference ''§ 1065.71(a)(2)(ii)'' in paragraph (b)(1)(iii) to ''§ 1065.71(a)(2)(v)'':

§ 1065.76 Payments by handler operating a partially regulated distributing plant.

* * * * *

(a) * * *

(4) Multiply the remaining pounds by the amount by which the Class I differential price exceeds the producer price differential, both prices to be applicable at the location of the partially regulated distributing plant, with the difference to be not less than zero;

* * * * *

(b) * * *

(1) * * *

(ii) * * * Any such transfers remaining after the above allocation which are classified in Class I and for which a value is computed for the handler operating the partially regulated distributing plant pursuant to § 1065.60 shall be priced at the statistical uniform price (or at the weighted average price if such is provided) of the respective order regulating the handling of milk at the transferee-plant, with such statistical uniform price adjusted to the location of the nonpool plant (but not to be less than the lowest class price of the respective order), except that transfers of reconstituted skim milk in filled milk shall be priced at the lowest class price of the respective order; and

* * * * *

PART 1068—MILK IN THE UPPER MIDWEST MARKETING AREA

1. Section 1068.30 is amended by revising paragraphs (a) and (c) and removing paragraph (d), to read as follows:

§ 1068.30 Reports of receipts and utilization.

* * * * *

(a) Each handler described in § 1068.9 (a), (b), and (c) shall report for each of its operations the following information:

(1) Product pounds, pounds of butterfat, pounds of protein, pounds of solids-not-fat other than protein (other solids), and the value of the somatic cell adjustment contained in or represented by:

(i) Receipts of producer milk, including producer milk diverted by the handler; and

(ii) Receipts of milk from handlers described in § 1068.9(c).

(2) Product pounds and pounds of butterfat contained in:

(i) Receipts by transfer or diversion of bulk fluid milk products from pool plants;

(ii) Receipts of fluid milk products not included in paragraphs (a)(1) or (a)(2)(i) of this section and bulk fluid cream products from any source;

(iii) Receipts of other source milk; and

(iv) Inventories at the beginning and end of the month of fluid milk products and products specified in § 1068.40(b)(1).

(3) The utilization or disposition of all milk, filled milk, and milk products required to be reported pursuant to this paragraph.

(4) Such other information with respect to the receipts and utilization of skim milk, butterfat, milk protein, other nonfat solids, and somatic cell information, as the market administrator may prescribe.

* * * * *

(c) Each handler not specified in paragraphs (a) and (b) of this section shall report with respect to its receipts and utilization of milk, filled milk, and milk products in such manner as the market administrator may prescribe.

2. Section 1068.31 is amended by revising paragraph (a) to read as follows:

§ 1068.31 Payroll reports.

(a) On or before the 22nd day of each month, each handler described in § 1068.9 (a), (b), and (c) shall report to the market administrator its producer payroll for such month, in the detail prescribed by the market administrator, showing for each producer the information described in § 1068.73(f).

* * * * *

3. Section 1068.50 is amended by revising the section heading, introductory text and paragraph (a), and adding paragraphs (e) through (l) to read as follows:

§ 1068.50 Class and component prices.

Subject to the provisions of § 1068.52, the class prices per hundredweight of milk containing 3.5 percent butterfat and the component prices for the month shall be as follows:

(a) *Class I price.* The Class I price shall be the basic formula price for the second preceding month plus $1.20.

* * * * *

(e) *Class I differential price.* The Class I differential price shall be the difference between the current month's Class I and Class III prices (this price may be negative).

(f) *Class II differential price.* The Class II differential price shall be the difference between the current month's Class II and Class III prices (this price may be negative).

(g) *Class III–A differential price.* The Class III–A differential price shall be the difference between the current month's Class III and Class III–A prices (this price may be negative).

(h) *Skim milk price.* The skim milk price per hundredweight, rounded to the nearest cent, shall be the Class III price less an amount computed by multiplying the butterfat differential by 35.

(i) *Butterfat price.* The butterfat price per pound, rounded to the nearest one-hundredth cent, shall be the Class III price plus an amount computed by multiplying the butterfat differential by 965 and dividing the resulting amount by one hundred.

(j) *Protein price.* The protein price per pound, rounded to the nearest one-hundredth cent, shall be 1.32 times the average monthly price per pound for 40-pound block Cheddar cheese on the National Cheese Exchange as reported by the Department.

(k) *Other solids price.* Other solids are herein defined as solids-not-fat other than protein. The other solids price per pound, rounded to the nearest one-hundredth cent, shall be the basic formula price at test less the average butterfat test of the basic formula price as reported by the Department times the butterfat price, less the average protein test of the basic formula price as reported by the Department for the month times the protein price, and dividing the resulting amount by the average other solids test of the basic formula price as reported by the Department. If the resulting price is less than zero, then the protein price will be reduced so that the other solids price equals zero.

(l) *Somatic cell adjustment.* (1) The somatic cell adjustment rate, per 1,000 somatic cells, rounded to five decimal places, shall be computed by multiplying .0005 times the monthly cheddar cheese price as defined in paragraph (j) of this section.

(2) The somatic cell adjustment per hundredweight shall be determined by subtracting from 350 the somatic cell count (in thousands) of the milk, multiplying the difference by the somatic cell adjustment rate, and rounding to the nearest full cent.

4. Section 1068.53, including the section heading, is revised to read as follows:

§ 1068.53 Announcement of class and component prices.

On or before the 5th day of the month, the market administrator shall announce the following prices:

(a) The Class I price for the following month;

(b) The Class II price for the following month;

(c) The Class III price for the preceding month;

(d) The Class III–A price for the preceding month;

(e) The skim milk price for the preceding month;

(f) The butterfat price for the preceding month;

(g) The protein price for the preceding month;

(h) The other solids price for the preceding month;

(i) The somatic cell adjustment rate for the preceding month; and

(j) The butterfat differential for the preceding month.

5. The section heading in § 1068.60 and the undesignated centerheading preceding it, the introductory text and paragraphs (a), (f), and (g), are revised to read as follows:

Producer Price Differential

§ 1068.60 Handler's value of milk.

For the purpose of computing a handler's obligation for producer milk, the market administrator shall determine for each month the value of milk of each handler described in § 1068.9 (a), (b), and (c).

(a) The handler's obligation for producer milk shall be computed as follows:

(1) Multiply the total hundredweight of producer milk in Class I as determined pursuant to § 1068.43(a) and § 1068.44(c) by the Class I differential price for the month;

(2) Add an amount obtained by multiplying the total hundredweight of producer milk in Class II as determined pursuant to § 1068.43(a) and § 1068.44(c) by the Class II differential price for the month;

(3) Add an amount obtained by multiplying the hundredweight of skim milk in Class I as determined pursuant to § 1068.43(a) and § 1068.44(a) by the skim milk price;

(4) Add an amount obtained by multiplying the pounds of skim milk in Class II and Class III as determined pursuant to § 1068.43(a) and § 1068.44(a) by the average protein content of producer skim milk received by the handler, and multiplying the resulting pounds of protein by the protein price;

(5) Add an amount obtained by multiplying the pounds of skim milk in Class II and Class III as determined pursuant to § 1068.43(a) and § 1068.44(a) by the average other solids content of producer skim milk received by the handler, and multiplying the resulting pounds of other solids by the other solids price.

(6) Add an adjustment for somatic cell content determined by multiplying the value reported pursuant to § 1068.30(a)(1) by the percentage of the total producer milk assigned to Class II and Class III pursuant to §§ 1068.43(a) and 1068.44(c); and

(7) Add an amount obtained by multiplying the total hundredweight of producer milk eligible to be priced as Class III–A by the Class III–A differential price for the month.

* * * * *

(f) Add the amount obtained from multiplying the Class I differential price

applicable at the location of the nearest unregulated supply plants from which an equivalent volume was received by the pounds of skim milk and butterfat in receipts of concentrated fluid milk products assigned to Class I pursuant to § 1068.43(e) and § 1068.44(a)(7)(i) and the pounds of skim milk and butterfat subtracted from Class I pursuant to § 1068.44(a)(11) and the corresponding steps of § 1068.44(b), excluding such skim milk and butterfat in receipts of bulk fluid milk products from an unregulated supply plant to the extent that an equivalent amount of skim milk or butterfat disposed of to such plant by handlers fully regulated under any Federal milk order is classified and priced as Class I milk and is not used as an offset for any other payment obligation under any order;

(g) Subtract, for a handler described in § 1068.9(c), the amount charged the preceding month for the skim milk and butterfat contained in inventory at the beginning of the month that was delivered to a pool plant during the month;

* * * * *

6. Section 1068.61 is amended by revising the section heading, introductory text, and paragraphs (a) and (e), to read as follows:

§ 1068.61 Producer price differential.

For each month the market administrator shall compute a producer price differential per hundredweight of milk as follows:

(a) Combine into one total for all handlers:

(1) The estimated values computed pursuant to § 1068.60 (a)(1), (a)(2), (a)(7) and (b) through (j) for all handlers; and

(2) Add the estimated values computed pursuant to § 1068.60 (a)(3), (a)(4), (a)(5) and (a)(6); and subtract the values obtained by multiplying the handlers' total pounds of protein and total pounds of other solids contained in such milk by their respective prices, and the total value of the somatic cell adjustment.

* * * * *

(e) Subtract not less than 4 cents nor more than 5 cents from the price computed pursuant to paragraph (d) of this section. The result shall be the ''producer price differential'' for milk received from producers.

7. Section 1068.62 is revised to read as follows:

§ 1068.62 Announcement of producer prices.

On or before the 12th day after the end of each month, the market administrator shall announce the following prices and information:

(a) The producer price differential;

(b) The protein price;

(c) The other solids price;

(d) The butterfat price;

(e) The somatic cell adjustment rate;

(f) The average butterfat, protein and other solids content of producer milk; and

(g) The statistical uniform price for milk containing 3.5 percent butterfat, computed by combining the Class III price and the producer price differential.

8. Section 1068.71 is amended by revising paragraph (a) to read as follows:

§ 1068.71 Payments to the producer-settlement fund.

(a) On or before the 16th day after the end of the month, each handler shall pay to the market administrator the amount, if any, by which the amount specified in paragraph (a)(1) of this section exceeds the amount specified in paragraph (a)(2) of this section:

(1) The total value of milk of the handler for such month as determined pursuant to § 1068.60.

(2) The sum of:

(i) The value of such handler's receipts of producer milk and milk received from a handler described in § 1068.9(c). In the case of a handler described in § 1068.9(c), less the amount due from other handlers pursuant to § 1068.73(d). The value of producer milk shall be computed as follows:

(A) An amount obtained by multiplying the total hundredweight of producer milk by the producer price differential as adjusted pursuant to § 1068.75;

(B) An amount obtained by multiplying the total pounds of protein contained in producer milk by the protein price;

(C) An amount obtained by multiplying the total pounds of other solids contained in producer milk by the other solids price;

(D) The total value of the somatic cell adjustment to producer milk; and

(ii) An amount obtained by multiplying the pounds of skim milk and butterfat for which a value was computed pursuant to § 1068.60(f) by the producer price differential as adjusted pursuant to § 1068.52 for the location of the plant from which received.

* * * * *

9. Sections 1068.73, 1068.74, and 1068.75 are revised to read as follows:

§ 1068.73 Payments to producers and to cooperative associations.

Each handler shall pay for milk received from producers or cooperative associations as follows:

(a) On or before the 25th day of the month, each handler shall pay for skim milk and butterfat received during the first 15 days of the month from a cooperative association:

(1) That is a handler pursuant to § 1068.9(a), at not less than the Class I price for the month at the location of the transferee or transferor plant, whichever is higher, adjusted by the butterfat differential for the preceding month;

(2) That is a handler pursuant to § 1068.9(c), at not less than the statistical uniform price at its plant location for the preceding month, adjusted by the butterfat differential for the preceding month; and

(3) That is not a handler but which is authorized to collect payment on behalf of its member producers and has requested that payment be made to it in aggregate, at not less than the statistical uniform price at its plant location for the preceding month, adjusted by the butterfat differential for the preceding month.

(b) On or before the 4th day after the end of the month, each handler shall pay for skim milk and butterfat received during the first 15 days of the month from a producer for whom payment is not being made pursuant to paragraph (a) of this section and who has not discontinued shipping to such handler, at not less than the statistical uniform price at its plant location for the preceding month, adjusted by the butterfat differential for the preceding month.

(c) On or before the 11th day after the end of the month, each handler shall pay for milk received and classified during the month from a cooperative association which is a handler pursuant to § 1068.9(a) adjusted at the location of the transferee or transferor plant, whichever is higher, payment shall be determined as follows:

(1) The hundredweight of Class I milk received times the Class I differential price for the month plus the pounds of Class I skim milk times the skim milk price for the month;

(2) The hundredweight of Class II milk received times the Class II differential price for the month;

(3) The hundredweight of Class III–A milk received times the Class III–A differential price for the month;

(4) The pounds of butterfat received times the butterfat price for the month;

(5) The pounds of protein received in Class II and Class III milk times the protein price for the month;

(6) The pounds of other solids received in Class II and Class III milk times the other solids price for the month;

(7) The hundredweight of Class II and Class III milk received times the somatic cell adjustment; and

(8) Less any payment made pursuant to paragraph (a)(1) of this section.

(d) On or before the 18th day after the end of the month, each handler shall make payment as described in this paragraph to:

(1) A cooperative association that is a handler pursuant to § 1068.9(c);

(2) A cooperative association that is not a handler but which is authorized to collect payment on behalf of its member producers and has requested that payment be made to it in aggregate;

(3) A producer for whom payment is not being made pursuant to paragraph (d) (1) and (2) of this section.

(4) Payment shall be determined by:

(i) The hundredweight of producer milk received times the producer price differential as adjusted pursuant to § 1068.75;

(ii) The pounds of butterfat received times the butterfat price for the month;

(iii) The pounds of protein received times the protein price for the month;

(iv) The pounds of other solids received times the other solids price for the month;

(v) The hundredweight of milk received times the somatic cell adjustment for the month; and

(vi) Less any payment made pursuant to paragraph (a) or (b) of this section.

(e) In making payments pursuant to paragraphs (a) (2) and (3), (b) and (d) of this section, deductions may be made for marketing services pursuant to § 1068.86 and for any proper deductions authorized by the producer. In the event a handler has not received full payment from the market administrator pursuant to § 1068.72 by the 18th day of the month, the handler may reduce pro rata its payments to producers pursuant to paragraph (d) by not more than the amount of such underpayment. Following receipt of the balance due from the market administrator, the handler shall complete payments to producers not later than the next payment date provided under this section.

(f) In making payment to individual producers as required by this section, each handler shall furnish each producer from whom it received milk a supporting statement, in such form that it may be retained by the producer, which shall show:

(1) The month and the identity of the handler and producer;

(2) The total pounds of milk received from the producer;

(3) The total pounds of butterfat contained in the producer's milk;

(4) The total pounds of protein contained in the producer's milk;

(5) The total pounds of other solids contained in the producer's milk;

(6) The somatic cell count of the producer's milk;

(7) The minimum rate or rates at which payment to the producer is required pursuant to this section;

(8) The rate that is used in making payment if such rate is other than the applicable minimum;

(9) The amount, or the rate per hundredweight, or rate per pound of component, of each deduction claimed by the handler, including any deduction claimed under § 1068.86, together with a description of the respective deductions; and

(10) The net amount of the payment to the producer.

§ 1068.74 Butterfat differential.

The butterfat differential, rounded to the nearest one-tenth cent, shall be 0.138 times the current month's butter price less 0.0028 times the preceding month's average pay price per hundredweight, at test, for manufacturing grade milk in Minnesota and Wisconsin, using the ''base month'' series, adjusted pursuant to § 1068.51 (a) through (e), as reported by the Department. The butter price means the simple average for the month of the Chicago Mercantile Exchange Grade A butter price as reported by the Department.

§ 1068.75 Plant location adjustments for producers and on nonpool milk.

(a) The producer price differential for producer milk received at a pool plant or delivered to a nonpool plant shall be adjusted according to the location of the plant of actual receipt at the rates set forth in § 1068.52.

(b) The producer price differential applicable to other source milk shall be adjusted at the rates set forth in § 1068.52, except that the adjusted producer price differential shall not be less than zero.

10. Section 1068.76 is amended by revising paragraph (a)(4) and the third sentence of paragraph (b)(1)(ii) to read as follows:

§ 1068.76 Payments by handler operating a partially regulated distributing plant.

* * * * *

(a) * * *

(4) Multiply the remaining pounds by the amount by which the Class I differential price exceeds the producer price differential, both prices to be applicable at the location of the partially regulated distributing plant, with the difference to be not less than zero;

* * * * *

(b) * * *

(1) * * *

(ii) * * * Any such transfers remaining after the above allocation which are classified in Class I and for which a value is computed for the handler operating the partially regulated distributing plant pursuant to § 1068.60 shall be priced at the statistical uniform price (or at the weighted average price if such is provided) of the respective order regulating the handling of milk at the transferee-plant, with such statistical uniform price adjusted to the location of the nonpool plant (but not to be less than the lowest class price of the respective order), except that transfers of reconstituted skim milk in filled milk shall be priced at the lowest class price of the respective order; and

* * * * *

§ 1068.85 [Amended]

11. Section 1068.85 is amended by changing the word ''15th'' in the introductory text to ''16th.''

§ 1068.86 [Amended]

12. Section 1068.86 is amended by changing the word ''15th'' in paragraphs (a) and (b) to ''16th.''

PART 1076—MILK IN THE EASTERN SOUTH DAKOTA MARKETING AREA

1. Section 1076.30 is amended by revising paragraphs (a) and (c) and removing paragraph (d) to read as follows:

§ 1076.30 Reports of receipts and utilization.

* * * * *

(a) Each handler described in § 1076.9(a), (b), and (c) shall report for each of its operations the following information:

(1) Product pounds, pounds of butterfat, pounds of protein, pounds of solids-not-fat other than protein (other solids), and the value of the somatic cell adjustment contained in or represented by:

(i) Receipts of producer milk, including producer milk diverted by the handler; and

(ii) Receipts of milk from handlers described in § 1076.9(c);

(2) Product pounds and pounds of butterfat contained in:

(i) Receipts by transfer or diversion of bulk fluid milk products from pool plants;

(ii) Receipts of fluid milk products not included in paragraph (a)(1) or (a)(2)(i) of this section and bulk fluid cream products from any source;

(iii) Receipts of other source milk; and

(iv) Inventories at the beginning and end of the month of fluid milk products

and products specified in § 1076.40(b)(1).

(3) The utilization or disposition of all milk, filled milk, and milk products required to be reported pursuant to this paragraph.

(4) Such other information with respect to the receipts and utilization of skim milk, butterfat, milk protein, other nonfat solids, and somatic cell information, as the market administrator may prescribe.

* * * * *

(c) Each handler not specified in paragraphs (a) and (b) of this section shall report with respect to its receipts and utilization of milk, filled milk, and milk products in such manner as the market administrator may prescribe.

2. Section 1076.31 is amended by revising paragraph (a) to read as follows:

§ 1076.31 Payroll reports.

(a) On or before the 20th day after the end of each month, each handler described in § 1076.9(a), (b), and (c) shall report to the market administrator its producer payroll for such month, in the detail prescribed by the market administrator, showing for each producer the information described in § 1076.73(e).

* * * * *

3. Section 1076.50 is amended by revising the section heading, introductory text and paragraph (a), reserving paragraph (d), and adding paragraphs (e) through (l):

§ 1076.50 Class and component prices.

Subject to the provisions of § 1076.52, the class prices per hundredweight of milk containing 3.5 percent butterfat and the component prices for the month shall be as follows:

(a) *Class I price.* The Class I price for the month per hundredweight of milk containing 3.5 percent butterfat shall be the basic formula price for the second preceding month plus $1.50.

* * * * *

(d) [Reserved]

(e) *Class I differential price.* The Class I differential price shall be the difference between the current month Class I and Class III prices (this price may be negative).

(f) *Class II differential price.* The Class II differential price shall be the difference between the current month Class II and Class III prices (this price may be negative).

(g) [Reserved]

(h) *Skim milk price.* The skim milk price per hundredweight, rounded to the nearest cent, shall be the Class III price less an amount computed by multiplying the butterfat differential by 35.

(i) *Butterfat price.* The butterfat price per pound, rounded to the nearest one-hundredth cent, shall be the Class III price plus an amount computed by multiplying the butterfat differential by 965 and dividing the resulting amount by one hundred.

(j) *Protein price.* The protein price per pound, rounded to the nearest one-hundredth cent, shall be 1.32 times the average monthly price per pound for 40-pound block Cheddar cheese on the National Cheese Exchange as reported by the Department.

(k) *Other solids price.* Other solids are herein defined as solids not fat other than protein. The other solids price per pound, rounded to the nearest one-hundredth cent, shall be the basic formula price at test less the average butterfat test of the basic formula price as reported by the Department times the butterfat price, less the average protein test of the basic formula price as reported by the Department for the month times the protein price, and dividing the resulting amount by the average other solids test of the basic formula price as reported by the Department. If the resulting price is less than zero, then the protein price will be reduced so that the other solids price equals zero.

(l) *Somatic cell adjustment.* (1) The somatic cell adjustment rate, per 1,000 somatic cells, rounded to five decimal places, shall be computed by multiplying .0005 times the monthly cheddar cheese price as defined in paragraph (j) of this section.

(2) The somatic cell adjustment, per hundredweight, shall be determined by subtracting from 350 the somatic cell count (in thousands) of the milk, multiplying the difference by the somatic cell adjustment rate, and rounding to the nearest full cent.

4. Section 1076.53 is revised to read as follows:

§ 1076.53 Announcement of class and component prices.

On or before the 5th day of the month, the market administrator shall announce the following prices:

(a) The Class I price for the following month;

(b) The Class II price for the following month;

(c) The Class III price for the preceding month;

(d) [Reserved]

(e) The skim milk price for the preceding month;

(f) The butterfat price for the preceding month;

(g) The protein price for the preceding month;

(h) The other solids price for the preceding month;

(i) The somatic cell adjustment rate for the preceding month; and

(j) The butterfat differential for the preceding month.

5. The section heading in § 1076.60 and the undesignated centerheading preceding it, the introductory text, and paragraphs (a) and (f) are revised to read as follows:

Producer Price Differential

§ 1076.60 Handler's value of milk.

For the purpose of computing a handler's obligation for milk the market administrator shall determine for each month the value of milk of each handler described in § 1076.9(a) with respect to each of its pool plants and each handler described in § 1076.9(b) and (c).

(a) The handler's obligation for producer milk and milk received from a handler described in § 1076.9(c) shall be computed as follows:

(1) Multiply the total hundredweight of milk in Class I as determined pursuant to § 1076.43(a) and § 1076.44(c) by the Class I differential price for the month;

(2) Add an amount obtained by multiplying the total hundredweight of milk in Class II as determined pursuant to § 1076.43(a) and § 1076.44(c) by the Class II differential price for the month;

(3) Add an amount obtained by multiplying the hundredweight of skim milk in Class I as determined pursuant to § 1076.43(a) and § 1076.44(a) by the skim milk price;

(4) Add an amount obtained by multiplying the pounds of skim milk in Class II and Class III as determined pursuant to § 1076.43(a) and § 1076.44(a) by the average protein content of the skim milk received by the handler, and multiplying the resulting pounds of protein by the protein price;

(5) Add an amount obtained by multiplying the pounds of skim milk in Class II and Class III as determined pursuant to § 1076.43(a) and § 1076.44(a) by the average other solids content of the skim milk received by the handler, and multiplying the resulting pounds of other solids by the other solids price; and

(6) Add an adjustment for somatic cell content determined by multiplying the value reported pursuant to § 1076.30(a)(1) by the percentage of the total producer milk assigned to Class II and Class III pursuant to §§ 1076.43(a) and 1076.44(c); and

* * * * *

(f) Add the amount obtained from multiplying the Class I differential price applicable at the location of the nearest unregulated supply plants from which an equivalent volume was received by

the pounds of skim milk and butterfat in receipts of concentrated fluid milk products assigned to Class I pursuant to § 1076.43(d) and § 1076.44(a)(7)(i) and the pounds of skim milk and butterfat subtracted from Class I pursuant to § 1076.44(a)(11) and the corresponding steps of § 1076.44(b), excluding such skim milk and butterfat in receipts of bulk fluid milk products from an unregulated supply plant to the extent that an equivalent amount of skim milk or butterfat disposed of to such plant by handlers fully regulated under any Federal milk order is classified and priced as Class I milk and is not used as an offset for any other payment obligation under any order;

* * * * *

6. Section 1076.61 is amended by revising the section heading, introductory text, and paragraphs (a) and (e), to read as follows:

§ 1076.61 Producer price differential.

For each month the market administrator shall compute a producer price differential per hundredweight of milk received from producers as follows:

(a) Combine into one total for all handlers:

(1) The values computed pursuant to § 1076.60, paragraphs (a)(1), (a)(2), and (b) through (i) for all handlers;

(2) Add values computed pursuant to § 1076.60(a)(3), (a)(4), (a)(5) and (a)(6); and subtract the values obtained by multiplying the handlers' total pounds of protein and total pounds of other solids contained in such milk by their respective prices, and the total value of the somatic cell adjustment.

* * * * *

(e) Subtract not less than 4 cents nor more than 5 cents from the price computed pursuant to paragraph (d) of this section. The result shall be the ''producer price differential.''

7. Section 1076.62 is revised to read as follows:

§ 1076.62 Announcement of producer prices.

On or before the 12th day after the end of each month, the market administrator shall announce the following prices and information:

(a) The producer price differential;

(b) The protein price;

(c) The other solids price;

(d) The butterfat price;

(e) The somatic cell adjustment rate;

(f) The average butterfat, protein and other solids content of producer milk and milk received from a handler described in § 1076.9(c); and

(g) The statistical uniform price for milk containing 3.5 percent butterfat, computed by combining the Class III price and the producer price differential.

8. Section 1076.71 is amended by revising paragraph (a)(2) to read as follows:

§ 1076.71 Payments to the producer-settlement fund.

(a) * * *

(2) The sum of:

(i) An amount obtained by multiplying the total hundredweight of producer milk and milk received from a handler described in § 1076.9(c) by the producer price differential as adjusted pursuant to § 1076.75;

(ii) An amount obtained by multiplying the total pounds of protein contained in producer milk and milk received from a handler described in § 1076.9(c) by the protein price;

(iii) An amount obtained by multiplying the total pounds of other solids contained in producer milk and milk received from a handler described in § 1076.9(c) by the other solids price;

(iv) The total value of the somatic cell adjustment to producer milk and milk received from handlers described in § 1076.9(c); and

(v) An amount obtained by multiplying the pounds of skim milk and butterfat for which a value was computed pursuant to § 1076.60(f) by the producer price differential as adjusted pursuant to § 1076.52 for the location of the plant from which received.

* * * * *

§ 1076.72 [Amended]

9. Section 1076.72 is amended by removing the last sentence.

10. Section 1076.73 is amended by revising paragraphs (a), (c), (d) and (e) to read as follows:

§ 1076.73 Payments to producers and to cooperative associations.

(a) Each handler shall pay each producer for milk received from producers for which payment is not made to a cooperative association pursuant to paragraph (b) or (c) of this section as follows:

(1) On or before the last day of each month, for producer milk received during the first 15 days of the month at a rate per hundredweight not less than the Class III price for the preceding month; and

(2) On or before the 18th day after the end of the month, payment for producer milk received during such month shall not be less than the sum of:

(i) The hundredweight of producer milk received times the producer price differential as adjusted pursuant to § 1076.75;

(ii) The pounds of butterfat received times the butterfat price for the month;

(iii) The pounds of protein received times the protein price for the month;

(iv) The pounds of other solids received times the other solids price for the month;

(v) The hundredweight of milk received times the somatic cell adjustment for the month;

(vi) Less any payment made pursuant to paragraph (a)(1) of this section;

(vii) Less proper deductions authorized in writing by such producer and plus or minus adjustments for errors in previous payments made to such producer;

(viii) Less deductions for marketing services pursuant to § 1076.86; and

(ix) If by such date the handler has not received full payment from the market administrator pursuant to § 1076.72 for such month, it may reduce pro rata its payment to producers by not more than the amount of such underpayment. Payment to producers shall be completed thereafter not later than the date for making payments pursuant to this paragraph next following receipt of the balance due from the market administrator.

* * * * *

(c) Each handler shall pay a cooperative association for milk received by the handler from a cooperative association acting as a handler described in § 1076.9(c) as follows:

(1) For milk received during the first 15 days of the month, the handler shall pay the cooperative association on or before the 28th day of the month during which the milk was received at a rate per hundredweight not less than the statistical uniform price computed pursuant to § 1076.62(g) for the preceding month; and

(2) For milk received during the month the handler shall pay the cooperative association on or before the 15th day after the end of the month during which the milk was received follows:

(i) The hundredweight of milk received times the producer price differential applicable at the location of the receiving handler's plant;

(ii) The pounds of butterfat received times the butterfat price for the month;

(iii) The pounds of protein received times the protein price for the month;

(iv) The pounds of other solids received times the other solids price for the month;

(v) The hundredweight of milk received times the somatic cell adjustment for the month; and

(vi) Less any payment made pursuant to paragraph (c)(1) of this section.

(d) Each handler shall pay a cooperative association for fluid milk products received by transfer from pool plant(s) operated by the cooperative association as follows:

(1) For milk received during the first 15 days of the month, the handler shall pay the cooperative association on or before the 28th day of the month during which the milk was received at a rate per hundredweight not less than the statistical uniform price computed pursuant to § 1076.62(g) adjusted by the butterfat differential, both for the preceding month; and

(2) For milk received and classified during the month the handler shall pay the cooperative association on or before the 15th day after the end of the month during which the milk was received, as follows:

(i) The hundredweight of Class I milk received times the Class I differential price for the month applicable at the transferee plant, plus the pounds of Class I skim milk times the skim milk price for the month;

(ii) The hundredweight of Class II milk received times the Class II differential price for the month,

(iii) [Reserved]

(iv) The pounds of butterfat received times the butterfat price for the month;

(v) The pounds of protein received in Class II and Class III milk times the protein price for the month;

(vi) The pounds of other solids received in Class II and Class III milk times the other solids price for the month;

(vii) The hundredweight of Class II and Class III milk received times the somatic cell adjustment; and

(viii) Less any payment made pursuant to paragraph (d)(1) of this section.

(e) In making payments for producer milk pursuant to paragraphs (a)(2) or (b)(2) of this section, each handler shall furnish each producer or cooperative association to whom such payment is made a supporting statement in such form that it may be retained by the recipient which shall show:

(1) The month and the identity of the producer;

(2) The daily and total pounds for each producer;

(3) The total pounds of butterfat contained in the producer's milk;

(4) The total pounds of protein contained in the producer's milk;

(5) The total pounds of other solids contained in the producer's milk;

(6) The somatic cell count of the producer's milk;

(7) The minimum rate or rates which payment to the producer is required pursuant to this order;

(8) The rate that is used in making payment if such rate is other than the applicable minimum rate;

(9) The amount, or the rate per hundredweight, or rate per pound of component, and the nature of each deduction claimed by the handler; and

(10) The net amount of payment to such producer or cooperative.

11. Sections 1076.74 and 1076.75 are revised to read as follows:

§ 1076.74 Butterfat differential.

The butterfat differential, rounded to the nearest one-tenth cent, shall be 0.138 times the current month's butter price less 0.0028 times the preceding month's average pay price per hundredweight, at test, for manufacturing grade milk in Minnesota and Wisconsin, using the ''base month'' series, adjusted pursuant to § 1076.51(a) through (e), as reported by the Department. The butter price means the simple average for the month of the Chicago Mercantile Exchange Grade A butter price as reported by the Department.

§ 1076.75 Plant location adjustments for producers and on nonpool milk.

(a) The producer price differential for producer milk shall be adjusted according to the location of the plant of actual receipt at the rates set forth in § 1076.52; and

(b) For the purpose of computations pursuant to § § 1076.71 and 1076.72 the producer price differential shall be adjusted at the rates set forth in § 1076.52 applicable at the location of the nonpool plant from which the milk was received, except that the adjusted producer price differential shall not be less than zero.

12. Section 1076.76 is amended by revising paragraphs (a)(4) and the last sentence of (b)(1)(ii) to read as follows, and changing the reference ''§ 1076.71(a)(2)(ii)'' in paragraph (b)(1)(iii) to ''§ 1076.71(a)(2)(v)'':

§ 1076.76 Payments by handler operating a partially regulated distributing plant.

* * * * *

(a) * * *

(4) Multiply the remaining pounds by the amount by which the Class I differential price exceeds the producer price differential, both price to be applicable at the location of the partially regulated distributing plant, with the difference to be not less than zero;

* * * * *

(b) * * *

(1) * * *

(ii) * * * Any such transfers remaining after the above allocation which are classified in Class I and for which a value is computed for the handler operating the partially regulated distributing plant pursuant to § 1076.60 shall be priced at the statistical uniform price (or at the weighted average price if such is provided) of the respective order regulating the handling of milk at the transferee-plant, with such statistical uniform price adjusted to the location of the nonpool plant (but not to be less than the lowest class price of the respective order), except that transfers of reconstituted skim milk in filled milk shall be priced at the lowest class price of the respective order; and

* * * * *

PART 1079—MILK IN THE IOWA MARKETING AREA

1. Section 1079.30 is amended by revising paragraphs (a) and (c) and removing paragraph (d), to read as follows:

§ 1079.30 Reports of receipts and utilization.

* * * * *

(a) Each handler described in § 1079.9(a), (b), and (c) shall report for each of its operations the following information:

(1) Product pounds, pounds of butterfat, pounds of protein, pounds of solids-not-fat other than protein (other solids), and the value of the somatic cell adjustment contained in or represented by:

(i) Receipts of producer milk, including producer milk diverted by the handler; and

(ii) Receipts of milk from handlers described in § 1079.9(c).

(2) Product pounds and pounds of butterfat contained in:

(i) Receipts by transfer or diversion of bulk fluid milk products from pool plants.

(ii) Receipts of fluid milk products not included in paragraph (a)(1) or (a)(2)(i) of this section and bulk fluid cream products from any source;

(iii) Receipts of other source milk;

(iv) Inventories at the beginning and end of the month of fluid milk products and products specified in § 1079.40(b)(1); and

(3) The utilization or disposition of all milk, filled milk, and milk products required to be reported pursuant to this paragraph.

(4) Such other information with respect to the receipts and utilization of skim milk, butterfat, milk protein, other nonfat solids, and somatic cell information, as the market administrator may prescribe.

* * * * *

(c) Each handler not specified in paragraphs (a) and (b) of this section

shall report with respect to its receipts and utilization of milk, filled milk, and milk products in such manner as the market administrator may prescribe.

2. Section 1079.31 is amended by revising paragraph (a) to read as follows:

§ 1079.31 Payroll reports.

(a) On or before the 22nd day after the end of each month, each handler described in § 1079.9(a), (b), or (c) shall report to the market administrator its producer payroll for such month in the detail prescribed by the market administrator, showing for each producer the information described in § 1079.73(e).

* * * * *

3. Section 1079.50 is amended by revising the section heading, introductory text and paragraph (a), and adding paragraphs (e) through (l) to read as follows:

§ 1079.50 Class and component prices.

Subject to the provisions of § 1079.52, the class prices per hundredweight of milk containing 3.5 percent butterfat and the component prices for the month shall be as follows:

(a) *Class I price.* The Class I price for the month per hundredweight of milk containing 3.5 percent butterfat shall be the basic formula price for the second preceding month plus $1.55.

* * * * *

(e) *Class I differential price.* The Class I differential price shall be the difference between the current month Class I and Class III prices (this price may be negative).

(f) *Class II differential price.* The Class II differential price shall be the difference between the current month Class II and Class III prices (this price may be negative).

(g) *Class III–A differential price.* The Class III–A differential price shall be the difference between the current month's Class III and Class III–A prices (this price may be negative).

(h) *Skim milk price.* The skim milk price per hundredweight, rounded to the nearest cent, shall be the Class III price less an amount computed by multiplying the butterfat differential by 35.

(i) *Butterfat price.* The butterfat price per pound, rounded to the nearest one-hundredth cent, shall be the Class III price plus an amount computed by multiplying the butterfat differential by 965 and dividing the resulting amount by one hundred.

(j) *Protein price.* The protein price per pound, rounded to the nearest one-hundredth cent, shall be 1.32 times the average monthly price per pound for 40-pound block Cheddar cheese on the National Cheese Exchange as reported by the Department.

(k) *Other solids price.* Other solids are herein defined as solids not fat other than protein. The other solids price per pound, rounded to the nearest one-hundredth cent, shall be the basic formula price at test less the average butterfat test of the basic formula price as reported by the Department times the butterfat price, less the average protein test of the basic formula price as reported by the Department for the month times the protein price, and dividing the resulting amount by the average other solids test of the basic formula price as reported by the Department. If the resulting price is less than zero, then the protein price will be reduced so that the other solids price equals zero.

(l) *Somatic cell adjustment.* (1) The somatic cell adjustment rate, per 1,000 somatic cells, rounded to five decimal places, shall be computed by multiplying .0005 times the monthly cheddar cheese price as defined in paragraph (j) of this section.

(2) The somatic cell adjustment, per hundredweight, shall be determined by subtracting from 350 the somatic cell count (in thousands) of the milk, multiplying the difference by the somatic cell adjustment rate, and rounding to the nearest full cent.

4. Section 1079.53 is revised to read as follows:

§ 1079.53 Announcement of class and component prices.

On or before the 5th day of the month, the market administrator shall announce the following prices:

(a) The Class I price for the following month;

(b) The Class II price for the following month;

(c) The Class III price for the preceding month;

(d) The Class III–A price for the preceding month;

(e) The skim milk price for the preceding month;

(f) The butterfat price for the preceding month;

(g) The protein price for the preceding month;

(h) The other solids price for the preceding month;

(i) The somatic cell adjustment rate for the preceding month; and

(j) The butterfat differential for the preceding month.

5. The section heading in § 1079.60 and the undesignated centerheading preceding it, the introductory text, and paragraphs (a), (f), and (g), are revised to read as follows:

Producer Price Differential

§ 1079.60 Handler's value of milk.

For the purpose of computing a handler's obligation for milk the market administrator shall determine for each month the value of milk of each handler described in § 1079.9(a) with respect to each of its pool plants, and each handler described in § 1079.9 (b) and (c).

(a) The handler's obligation for producer milk and milk received from a handler described in § 1079.9(c) shall be computed as follows:

(1) Multiply the total hundredweight of milk in Class I as determined pursuant to § 1079.43(a) and § 1079.44(c) by the Class I differential price for the month;

(2) Add an amount obtained by multiplying the total hundredweight of milk in Class II as determined pursuant to § 1079.43(a) and § 1079.44(c) by the Class II differential price for the month;

(3) Add an amount obtained by multiplying the hundredweight of skim milk in Class I as determined pursuant to § 1079.43(a) and § 1079.44(a) by the skim milk price;

(4) Add an amount obtained by multiplying the pounds of skim milk in Class II and Class III as determined pursuant to § 1079.43(a) and § 1079.44(a) by the average protein content of the skim milk received by the handler, and multiplying the resulting pounds of protein by the protein price;

(5) Add an amount obtained by multiplying the pounds of skim milk in Class II and Class III as determined pursuant to § 1079.43(a) and § 1079.44(a) by the average other solids content of the skim milk received by the handler, and multiplying the resulting pounds of other solids by the other solids price;

(6) Add an adjustment for somatic cell content determined by multiplying the value reported pursuant to § 1079.30(a)(1) by the percentage of the total producer milk assigned to Class II and Class III pursuant to §§ 1079.43(a) and 1079.44(c); and

(7) Add an amount obtained by multiplying the total hundredweight of producer milk eligible to be priced as Class III–A by the Class III–A differential price for the month.

* * * * *

(f) Add the amount obtained from multiplying the Class I differential price applicable at the location of the nearest unregulated supply plants from which an equivalent volume was received by the pounds of skim milk and butterfat in receipts of concentrated fluid milk products assigned to Class I pursuant to § 1079.43(d) and § 1079.44(a)(7)(i) and the pounds of skim milk and butterfat

subtracted from Class I pursuant to § 1079.44(a)(11) and the corresponding steps of § 1079.44(b), excluding such skim milk and butterfat in receipts of bulk fluid milk products from an unregulated supply plant to the extent that an equivalent amount of skim milk or butterfat disposed of to such plant by handlers fully regulated under any Federal milk order is classified and priced as Class I milk and is not used as an offset for any other payment obligation under any order;

(g) Subtract for a handler described in § 1079.9(c) the amount charged the preceding month for the skim milk and butterfat contained in inventory at the beginning of the month that was delivered to a pool plant during the month;

* * * * *

6. Section 1079.61 is amended by revising the section heading, introductory text, and paragraphs (a) and (e) to read as follows:

§ 1079.61 Producer price differential.

For each month the market administrator shall compute a producer price differential per hundredweight for Zone 1. If the unreserved cash balance in the producer settlement fund to be included in the computation is less than 2 cents per hundredweight of producer milk on all reports, the report of any handler who has not made the payments required pursuant to § 1079.71 for the preceding month shall not be included in the computation of the producer price differential. The report of such handler shall not be included in the computation for succeeding months until the handler has made full payment of outstanding monthly obligations. Subject to the aforementioned conditions, the market administrator shall compute the producer price differential in the following manner:

(a) Combine into one total for all handlers:

(1) The values computed pursuant to § 1079.60 (a)(1), (a)(2), (a)(7), and (b) through (j) for all handlers; and

(2) Add values computed pursuant to § 1079.60 (a)(3), (a)(4), (a)(5) and (a)(6); and subtract the values obtained by multiplying the handlers' total pounds of protein and total pounds of other solids contained in such milk by their respective prices, and the total value of somatic cell adjustments.

* * * * *

(e) Subtract not less than 4 cents nor more than 5 cents from the price computed pursuant to paragraph (d) of this section. The result shall be known as the ''producer price differential.''

7. Section 1079.62 is revised to read as follows:

§ 1079.62 Announcement of producer prices.

On or before the 12th day after the end of each month, the market administrator shall announce the following prices and information:

(a) The producer price differential;

(b) The protein price;

(c) The other solids price;

(d) The butterfat price;

(e) The somatic cell adjustment rate;

(f) The average butterfat, protein and other solids content of producer milk and milk received from a handler described in § 1079.9(c); and

(g) The statistical uniform price for milk containing 3.5 percent butterfat, computed by combining the Class III price and the producer price differential.

8. Section 1079.71 is amended by revising paragraph (a)(2) and reserving paragraph (b), to read as follows:

§ 1079.71 Payments to the producer-settlement fund.

(a) * * *

(2) The sum of:

(i) An amount obtained by multiplying the total hundredweight of producer milk and milk received from a handler described in § 1079.9(c) by the producer price differential as adjusted by § 1079.75. In the case of a handler described in § 1079.9(c), less the amount due from handlers pursuant to § 1079.73;

(ii) An amount obtained by multiplying the total pounds of protein contained in producer milk and milk received from a handler described in § 1079.9(c) by the protein price;

(iii) An amount obtained by multiplying the total pounds of other solids contained in producer milk and milk received from a handler described in § 1079.9(c) by the other solids price;

(iv) The total value of the somatic cell adjustment to producer milk and milk received from handlers described in § 1079.9(c); and

(v) An amount obtained by multiplying the pounds of skim milk and butterfat for which a value was computed pursuant to § 1079.60(f) by the producer price differential as adjusted pursuant to § 1079.52 for the location of the plant from which received.

(b) [Reserved]

9. Sections 1079.73, 1079.74 and 1079.75 are revised to read as follows:

§ 1079.73 Payments to producers and to cooperative associations.

(a) Each handler shall pay for milk received from producers for which payment is not made to a cooperative association pursuant to paragraph (b) or (c) of this section as follows:

(1) On or before the last day of each month, to each producer who has not discontinued shipping milk to such handler before the end of the month, for producer milk received during the first 15 days of the month at a rate per hundredweight not less than the statistical uniform price computed pursuant to § 1079.62(g) for the preceding month and adjusted pursuant to § 1079.75, less proper deductions authorized in writing by such producer; and

(2) On or before the 18th day after the end of the month, payment for producer milk received during such month shall not be less than the sum of:

(i) The hundredweight of producer milk received times the producer price differential adjusted pursuant to § 1079.75;

(ii) The pounds of butterfat received times the butterfat price for the month;

(iii) The pounds of protein received times the protein price for the month;

(iv) The pounds of other solids received times the other solids price for the month;

(v) The hundredweight of milk received times the somatic cell adjustment for the month;

(vi) Less any payment made pursuant to paragraph (a)(1) of this section;

(vii) Less proper authorized deductions authorized in writing by such producer and plus or minus adjustments for errors in previous payments made to such producer;

(viii) Less deductions for marketing services pursuant to § 1079.86; and

(ix) If by such date the handler has not received full payment from the market administrator pursuant to § 1079.72 for such month, it may reduce pro rata its payment to producers by not more than the amount of such underpayment. Payment to producers shall be completed thereafter not later than the date for making payments pursuant to this paragraph next following receipt of the balance due from the market administrator.

(b) Each handler shall pay a cooperative association as follows for milk received from producers if the cooperative association has filed a written request for payment with the handler and if the market administrator has determined that such cooperative association is authorized to collect payment:

(1) On or before the last day of the month, an amount not less than the sum of the individual payments otherwise payable to producers pursuant to paragraph (a)(1) of this section, less any deductions authorized in writing by such cooperative association; and

(2) On or before the 18th day after the end of each month an amount not less than the sum of the individual payments otherwise payable to producers pursuant to paragraph (a)(2) of this section, less proper deductions authorized in writing by such cooperative association.

(c) Each handler shall pay a cooperative association for milk received by the handler from a cooperative association acting as a handler described in § 1079.9(c) as follows:

(1) For milk received during the first 15 days of the month, the handler shall pay the cooperative association on or before the last day of the month during which the milk was received at a rate per hundredweight not less than the statistical uniform price computed pursuant to § 1079.62(g), applicable at the location of the receiving handler's plant, for the preceding month; and

(2) For milk received during the month the handler shall pay the cooperative association on or before the 18th day after the end of the month during which the milk was received as follows:

(i) The hundredweight of milk received times the producer price differential applicable at the location of the receiving handler's plant;

(ii) The pounds of butterfat received times the butterfat price for the month;

(iii) The pounds of protein received times the protein price for the month;

(iv) The pounds of other solids received times the other solids price for the month;

(v) The hundredweight of milk received times the somatic cell adjustment for the month;

(vi) Less any payment made pursuant to paragraph (c)(1) of this section;

(d) Each handler shall pay a cooperative association for fluid milk products received by transfer from pool plant(s) operated by a cooperative association as follows:

(1) For milk received during the first 15 days of the month, the handler shall pay the cooperative association on or before the last day of the month during which the milk was received at a rate per hundredweight not less than the statistical uniform price applicable at the transferee plant as computed pursuant to § 1079.62(g) and adjusted by the butterfat differential, both for the preceding month; and

(2) For milk received and classified during the month the handler shall pay the cooperative association on or before the 18th day after the end of the month during which the milk was received, as follows:

(i) The hundredweight of Class I milk received times the Class I differential price for the month applicable at the transferee plant, plus the pounds of Class I skim milk times the skim milk price for the month;

(ii) The hundredweight of Class II milk received times the Class II differential price for the month;

(iii) The hundredweight of Class III–A milk received times the Class III–A differential price for the month;

(iv) The pounds of butterfat received times the butterfat price for the month;

(v) The pounds of protein received in Class II and Class III milk times the protein price for the month;

(vi) The pounds of other solids received in Class II and Class III milk times the other solids price for the month;

(vii) The hundredweight of Class II and Class III milk received times the somatic cell adjustment; and

(viii) Less any payment made pursuant to paragraph (d)(1) of this section.

(e) In making payments for producer milk pursuant to paragraphs (a)(2) or (b)(2) of this section, each handler shall furnish each producer or cooperative association to whom such payment is made a supporting statement in such form that it may be retained by the recipient which shall show:

(1) The month and the identity of the producer;

(2) The daily and total pounds for each producer;

(3) The total pounds of butterfat contained in the producer's milk;

(4) The total pounds of protein contained in the producer's milk;

(5) The total pounds of other solids contained in the producer's milk;

(6) The somatic cell count of the producer's milk;

(7) The minimum rate or rates at which payment to the producer is required pursuant to this order;

(8) The rate that is used in making payment if such rate is other than the applicable minimum rate;

(9) The amount, rate per hundredweight, or rate per pound of component, and the nature of each deduction claimed by the handler; and

(10) The net amount of payment to such producer or cooperative.

§ 1079.74 Butterfat differential.

The butterfat differential, rounded to the nearest one-tenth cent, shall be 0.138 times the current month's butter price less 0.0028 times the preceding month's average pay price per hundredweight, at test, for manufacturing grade milk in Minnesota and Wisconsin, using the ''base month'' series, adjusted pursuant to § 1079.51(a) through (e), as reported by the Department. The butter price means the simple average for the month of the Chicago Mercantile Exchange Grade A butter price as reported by the Department.

§ 1079.75 Plant location adjustments for producers and on nonpool milk.

(a) The producer price differential for producer milk pursuant to § 1079.61 received at a pool plant or diverted from a pool plant shall be reduced according to the location of the plant of actual receipt at the rates set forth in § 1079.52.

(b) For purposes of computations pursuant to §§ 1079.71 and 1079.72 the producer price differential shall be adjusted at the rates set forth in § 1079.52 applicable at the location of the nonpool plant from which the milk was received, except that the adjusted producer price differential shall not be less than zero.

10. Section 1079.76 is amended by revising paragraph (a)(4) and the last sentence of paragraph (b)(1)(ii) to read as follows, and changing the reference ''§ 1079.71(a)(2)(ii)'' in paragraph (b)(1)(iii) to ''§ 1079.71(a)(2)(v)'':

§ 1079.76 Payments by handler operating a partially regulated distributing plant.

* * * * *

(a) * * *

(4) Multiply the remaining pounds by the amount by which the Class I differential price exceeds the producer price differential, both prices to be applicable at the location of the partially regulated distributing plant, with the difference to be not less than zero;

* * * * *

(b) * * *

(1) * * *

(ii) * * * Any such transfers remaining after the above allocation which are classified in Class I and for which a value is computed for the handler operating the partially regulated distributing plant pursuant to § 1079.60 shall be priced at the statistical uniform price (or at the weighted average price if such is provided) of the respective order regulating the handling of milk at the transferee-plant, with such statistical uniform price adjusted to the location of the nonpool plant (but not to be less than the lowest class price of the respective order), except that transfers of reconstituted skim milk in filled milk shall be priced at the lowest class price of the respective order; and

* * * * *

Marketing Agreement Regulating the Handling of Milk in Certain Marketing Areas

The parties hereto, in order to effectuate the declared policy of the Act, and in accordance with the rules of practice and procedure effective thereunder (7 CFR Part 900), desire to enter into this marketing agreement and do hereby agree that the provisions referred to in paragraph I hereof as augmented by the provisions specified in paragraph II hereof, shall be and are the provisions of this marketing agreement as if set out in full herein.

I. The findings and determinations, order relative to handling, and the provisions of §§ _____[1] to _____, all inclusive, of the order regulating the handling of milk in the (_____ Name of order _____) marketing area (7 CFR PART _____[2]) which is annexed hereto; and

II. The following provisions:

§ _____[3] Record of milk handled and authorization to correct typographical errors.

(a) Record of milk handled. The undersigned certifies that he/she handled during the month of December 1994, _____ hundredweight of milk covered by this marketing agreement.

(b) Authorization to correct typographical errors. The undersigned hereby authorizes the Director, or Acting Director, Dairy Division, Agricultural Marketing Service, to correct any typographical errors which may have been made in this marketing agreement.

§ _____[3] Effective date. This marketing agreement shall become effective upon the execution of a counterpart hereof by the Secretary in accordance with Section 900.14(a) of the aforesaid rules of practice and procedure.

In Witness Whereof, The contracting handlers, acting under the provisions of the Act, for the purposes and subject to the limitations herein contained and not otherwise, have hereunto set their respective hands and seals.

Signature

By (Name) _____

(Title) _____

(Address) _____

(Seal) _____

Attest _____

[FR Doc. 95–19677 Filed 8–11–95; 8:45 am]

BILLING CODE 3410–02–P

[1] First and last sections of order.

[2] Appropriate Part number.

[3] Next consecutive section number.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95–CE–26–AD]

Airworthiness Directives; Jetstream Aircraft Limited Model 3201 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to certain Jetstream Aircraft Limited (JAL) Model 3201 airplanes. The proposed action would require repetitively inspecting the main landing gear (MLG) bay forward lower edge wing skin structure for cracks, replacing any cracked doubler with a joggled doubler of improved design to reinforce the area and prevent future cracking, and eventually incorporating these doublers on all affected airplanes. Cracking found at the MLG bay forward lower edge wing skin structure during fatigue testing of the JAL Model 3201 airplanes prompted the proposed action. The actions specified by the proposed AD are intended to prevent the MLG bay forward lower edge wing skin structure from cracking, which, if not detected and corrected, could cause failure of the wing structure and loss of control of the airplane.

DATES: Comments must be received on or before October 8, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–26–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from Jetstream Aircraft Limited, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, telephone (44–292) 79888; facsimile (44–292) 79703; or Jetstream Aircraft Inc., Librarian, P.O. Box 16029, Dulles International Airport, Washington, DC 20041–6029; telephone (703) 406–1161; facsimile (703) 406–1469. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Raymond A. Stoer, Program Officer, Brussels Aircraft Certification Office, FAA, Europe, Africa, and Middle East Office, c/o American Embassy, B–1000 Brussels, Belgium; telephone (322) 513.3830; facsimile (322) 230.6899; or Mr. Marvin R. Nuss, Project Officer, Small Airplane Directorate, Airplane Certification Service, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64105; telephone (816) 426–6932; facsimile (816) 426–2169.

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 should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, 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 that summarizes 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 No 95–CE–26–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, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–26–AD, room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The Civil Airworthiness Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified the FAA that an unsafe condition may exist on certain JAL Model 3201 airplanes. The CAA advises that cracks may develop in the MLG bay forward lower edge wing skin structure adjacent to the main spar. While

undergoing fatigue tests of this airplane model, Jetstream discovered the tendency for cracking in this area.

JAL has issued Jetstream Service Bulletin (SB) 57–A–JA920540; Original Issue September 1, 1992, which specifies procedures for inspecting the MLG bay forward lower edge wing skin structure for cracks, and if cracks are found, replacing the cracked doubler with a new joggled doubler of an improved design.

In order to assure the continued airworthiness of these airplanes in the United Kingdom, the CAA classified this service bulletin as mandatory. The CAA classifying a service document as mandatory is the same for airplanes registered in the United Kingdom as the FAA issuing an AD for airplanes registered in the United States.

This airplane model is manufactured in the United Kingdom and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement between the United States and the United Kingdom.

Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop in other Jetstream Model 3201 airplanes of the same type design, the proposed AD would require repetitively inspecting the MLG bay forward lower edge wing skin structure adjacent to the main spar for cracks. If cracks are found, replace the cracked doubler with a joggled doubler of improved design to reinforce the area and prevent future cracking. Accomplishment of the proposed action would be in accordance with Jetstream Service Bulletin 57–A–JA920540; Original Issue September 1, 1992.

The proposed action would be consistent with the FAA's aging commuter-class aircraft policy. This policy simply states that reliance on critical repetitive inspections carries an unnecessary safety risk when a design change exists that could eliminate or, in certain instances, reduce the number of those critical inspections. Therefore, the proposed action, if incorporated as a final rule, would be consistent with the FAA's commuter-class aircraft policy.

The FAA estimates that 134 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 35 workhours per airplane to accomplish the proposed action, and that the average labor rate is approximately $60 an hour. Parts will be provided by the manufacturer at no cost to the owners/operators. Based on these figures, the total cost impact of the proposed AD on U.S. operator is estimated to be $281,400. This figure is based on the assumption that all of the affected airplanes do not have the new joggled doublers installed and that none of the owners/operators of the affected airplanes have replaced the doublers.

Jetstream has informed the FAA that parts have been distributed to equip approximately 5 airplanes. Assuming that these distributed parts are incorporated on the affected airplanes, the cost of the proposed AD would be reduced by $10,500 from $281,400 to $270,900.

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 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) 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 has been placed 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); 40101, 40113, 44701.

§ 39.13 [AMENDED]

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

Jetstream Aircraft Limited: Docket No. 95–CE–26–AD.

Applicability: Model 3201 airplanes (serial numbers 790 through 969), certificated in any category.

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

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

To prevent the main landing gear (MLG) by forward lower edge wing skin structure from cracking, which, if not detected and corrected, could cause failure of the wing structure and loss of control of the airplane, accomplish the following:

(a) Upon accumulating 4,000 hours time-in-service (TIS) or within the next 200 hours TIS after the effective date of this AD, whichever occurs later, inspect the MLG bay forward lower edge wing skin structure adjacent to the main spar for cracks in accordance with the Accomplishment Instructions section of Jetstream Service Bulletin (SB) 57–A–JA920540, Original Issue September 1, 1992.

(1) If cracks are found, prior to further flight, replace the existing doublers with joggled doublers of improved design in accordance with the Accomplishment Instructions section of Jetstream SB 57–A–JA920540, Original Issue September 1, 1992.

(2) If no cracks are found, re-inspect the MLG bay forward lower edge wing skin structure at intervals not to exceed 600 hours TIS until modified as specified in paragraph (b) of this AD.

(b) Upon accumulating 9,000 hours TIS or within the next 200 hours TIS after the effective date of this AD, whichever occurs later, unless already accomplished as specified in paragraph (a)(1) of this AD, replace the existing doublers with joggled doublers of improved design in accordance

with the Accomplishment Instructions section of Jetstream SB 57–A–JA920540.

(c) Replacing the joggled doublers as required by paragraphs (a)(1) or (b) of this AD eliminates the repetitive inspection requirements of this AD.

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

(e) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, Brussels Aircraft Certification Office, FAA, Europe, Africa, and Middle East Office, c/o American Embassy, B–1000 Brussels, Belgium. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Brussels Aircraft Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Brussels Aircraft Certification Office.

(f) All persons affected by this directive may obtain copies of the document referred to herein upon request to Jetstream Aircraft Limited, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, or Jetstream Aircraft Inc., Librarian, P.O. Box 16029, Dulles International Airport, Washington, D.C. 20041–6029; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on August 7, 1995.

Gerald W. Pierce,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–20004 Filed 8–11–95; 8:45 am]

BILLING CODE 4910–13–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 60, 260, 262, 264, 265, 270, and 271

[IL–64–2–5807; FRL–5277–1]

Hazardous Waste Treatment, Storage, and Disposal Facilities and Hazardous Waste Generators; Organic Air Emission Standards for Tanks, Surface Impoundments, and Containers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; data availability.

SUMMARY: This notice announces the availability of additional data that are being considered by the EPA in revising the air emission standards for hazardous waste treatment, storage, and disposal facilities (TSDF) that were published December 6, 1994 under the authority of the Resource Conservation and Recovery Act (RCRA), as amended (59 FR 62896). The additional data are available for public inspection at the EPA RCRA Docket Office.

DATES: Comments on these additional data will be accepted through October 13, 1995.

ADDRESSES: Docket. The additional data are available for public inspection and copying in the EPA RCRA Docket Office (5305), Room 2616, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460. A reasonable fee may be charged for copying. Docket hours are 9 a.m. to 4 p.m. Monday through Friday excluding Federal holidays. Other RCRA docket numbers that pertain to the final rule are F–91–CESP–FFFFF, F–92–CESA–FFFFF, F–94–CESF–FFFFF, and F–94–CE2A–FFFFF.

Comments. Written comments regarding these data may be mailed to the Docket Clerk (5305), Room 2616, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460. Please send an original and two copies of all comments, and refer to Docket Number F–95–CE3A–FFFFF. Comments on the additional data will be accepted through October 13, 1995.

FOR FURTHER INFORMATION CONTACT: For general information about this action contact the RCRA Hotline at (703) 412–9877 or toll-free at 1–800–424–9346. For information on specific technical aspects of these data contact Ms. Michele Aston, Emissions Standards Division (MD–13), U.S. EPA, Research Triangle Park, N.C. 27711, telephone (919) 541–2363, telefax (919) 541–3470.

SUPPLEMENTARY INFORMATION: On December 6, 1994, the EPA published in the **Federal Register** (59 FR 62896) under authority of the Resource Conservation and Recovery Act (RCRA), as amended, standards requiring the use of air emission controls on certain tanks, surface impoundments, and containers at hazardous waste treatment, storage, and disposal facilities (TSDF). These standards are codified in 40 CFR parts 264 and 265 under subpart CC (referred to as the ''subpart CC standards'').

Since publication of these final standards, the EPA has been involved in a review of its standards to identify areas in which regulatory measures can be made less burdensome without compromising environmental benefits. For the subpart CC standards, this effort has identified certain requirements of the final standards for which less extensive regulatory requirements may suffice. The EPA is considering revising the published standards to reflect the requirements described in the additional data. The sections of the published rule that are addressed by these additional data are: applicability, waste determination procedures, standards for tanks, standards for surface impoundments, standards for containers, inspection and monitoring requirements, recordkeeping requirements, and reporting requirements.

The EPA will consider these new data in the regulatory decision-making process for this regulation. Therefore, the new data are being placed into the RCRA docket for public inspection and review. To clearly distinguish these new data, they have been placed under a new docket number: F–95–CE3A–FFFFF. The EPA will consider all comments on the new data received by the close of the comment period when making a final regulatory determination on the regulatory requirements for this regulation.

These items are not the exclusive list of the provisions which the EPA is considering revising. The EPA is planning to publish a technical correction notice to the rule within the next two months, and may also propose additional changes to the rule in the near future.

List of Subjects

40 CFR Parts 264 and 265

Air pollution control, Container, Control device, Hazardous waste, Incorporation by reference, Inspection, Miscellaneous unit, Monitoring, Reporting and recordkeeping requirements, Standards, Surface impoundment, Tank, Waste determination.

Dated: August 9, 1995.

Richard Wilson,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 95–20003 Filed 8–11–95; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

Television Broadcasting Services; Bend, OR

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; denial of petition.

SUMMARY: This document denies the petition for reconsideration filed by

3–J Broadcasting Company, seeking review of the action taken by the Chief, Allocations Branch, on July 18, 1994, returning its petition for rule making by letter as unacceptable for consideration. 3–J Broadcasting Company petitioned for a waiver of the ATV *Freeze Order* (52 FR 28346, July 29, 1987) and the allotment of Channel 38 to Bend, Oregon, as the community's fourth local television service. The Commission has determined that 3–J Broadcasting Company has not met the criteria for grant of its waiver request. With this action, this proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Memorandum Opinion and Order*, adopted July 24, 1995, and released August 4, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Television broadcasting.

Federal Communications Commission.

Douglas W. Webbink,

Chief, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 95–19740 Filed 8–11–95; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 60, No. 156
Monday, August 14, 1995

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

Animal and Plant Health Inspection Service

[Docket No. 95–061–1]

General Conference Committee of the National Poultry Improvement Plan; Meeting

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of meeting.

SUMMARY: We are giving notice of a meeting of the General Conference Committee of the National Poultry Improvement Plan.

PLACE, DATES, AND TIME OF MEETING: The meeting will be held at the USDA Center at Riverside, 4700 River Road, Riverdale, MD, in room 5D01CN. Sessions will be held from 8 a.m. to 5 p.m. on September 19, 1995, and from 8 a.m. to 12 p.m. on September 20, 1995.

FOR FURTHER INFORMATION CONTACT: Mr. Andrew Rhorer, Senior Coordinator, National Poultry Improvement Plan, VS, APHIS, 1500 Klondike Road, Suite A 102, Conyers, GA, (404) 922–3496.

SUPPLEMENTARY INFORMATION: The General Conference Committee (the Committee) of the National Poultry Improvement Plan (NPIP), representing cooperating State agencies and poultry industry members, serves an essential function by acting as liaison between the poultry industry and the Department in matters pertaining to poultry health. In addition, this Committee assists the Department in planning, organizing, and conducting the NPIP Conference.

Tentative topics for discussion at the upcoming meeting include:

1. Establishing provisions in the NPIP for ostriches;
2. Removing certain NPIP provisions from the Code of Federal Regulations;
3. Avian Influenza surveillance;
4. Avian Mycoplasmosis, vaccination vs. eradication; and
5. Establishing a Salmonella Monitored classification.

The meeting will be open to the public. However, due to time constraints, the public will not be allowed to participate in the Committee's discussions. Written statements on meeting topics may be filed with the Committee before or after the meeting by sending them to the person listed under **FOR FURTHER INFORMATION CONTACT**. Written statements may also be filed at the meeting. Please refer to Docket No. 95–061–1 when submitting your statements.

This notice of meeting is given pursuant to section 10 of the Federal Advisory Committee Act.

Done in Washington, DC, this 7th day of August 1994.

Lonnie J. King,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–19913 Filed 8–11–95; 8:45 am]

BILLING CODE 3410–34–P

Forest Service

Environmental Impact Statement, Port Houghton/Cape Fanshaw Timber Sale(s), Tongass National Forest, Stikine and Chatham Areas, Petersburg and Sitka, Alaska

AGENCY: Forest Service, USDA.

ACTION: Revised notice of intent to prepare an environment impact statement.

SUMMARY: This Notice of Intent Revises the September 12, 1994 NOI (page 46819) by describing two changes:

1. Two decision-makers will sign the Record of Decision. The decision will be made by Abigail R. Kimbell, Forest Supervisor of the Stikine Area, and by Gary Morrison, Forest Supervisor of the Chatham Area of the Tongass National Forest.

2. The Draft EIS is now scheduled for publication in September 1995 and the Final EIS in March 1996.

FOR FURTHER INFORMATION CONTACT: Questions, written comments, and suggestions concerning the analysis should be sent to Tom Parker, USDA Forest Service, PO Box 1328, Petersburg, AK 99833, phone (907) 772–3871, fax (907) 772–3141.

Dated: August 3, 1995.

Abigail R. Kimbell,

Stikine Area Forest Supervisor.

Dated: July 28, 1995.

Gary A. Morrison,

Chatham Area Forest Supervisor.

[FR Doc. 95–19952 Filed 8–11–95; 8:45 am]

BILLING CODE 3410–11–M

Eastern Washington Cascades Provincial Interagency Executive Committee (PIEC), Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Eastern Washington Cascade PIEC Advisory Committee will meet on September 7, 1995 in Campbell's Conference Center (River Room), 104 W. Wooden, Chelan, Washington. The meeting will begin at 9 a.m. and continue until 4 p.m. This session will focus on forest health in dry eastside forest ecosystems. All Eastern Washington Cascades Province Advisory Committee meetings are open to the public. Interested citizens are welcome to attend.

FOR FURTHER INFORMATION CONTACT: Direct questions regarding this meeting to Paul Hart, Designated Federal Official, USDA, Wenatchee National Forest, P.O. Box 811, Wenatchee, Washington 98807, 509–662–4335.

Dated: August 1, 1995.

Paul Hart,

Designated Federal Official, Wenatchee National Forest.

[FR Doc. 95–19955 Filed 8–11–95; 8:45 am]

BILLING CODE 3410–11–M

Yakima Provincial Interagency Executive Committee (PIEC), Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Yakima PIEC Advisory Committee will meet on August 24, 1995 at the Hal Holmes Conference Center, 201 N. Ruby, Ellensburg, Washington. The meeting will begin at 9 a.m. and continue until 4 p.m. This meeting will focus on key challenges identified by the committee: (1) Forest health in dry eastside forest ecosystems, (2) riparian zone protection, and (3)

access and travel management. All Yakima Province Advisory Committee meetings are open to the public. Interested citizens are welcome to attend.

FOR FURTHER INFORMATION CONTACT: Direct questions regarding this meeting to Paul Hart, Designated Federal Official, USDA, Wenatchee National Forest, P.O. Box 811, Wenatchee, Washington. 98807, 509–662–4335.

Dated: August 1, 1995.

Paul Hart,

Designated Federal Official, Wenatchee National Forest.

[FR Doc. 95–19954 Filed 8–11–95; 8:45 am]

BILLING CODE 3410–11–M

CIVIL RIGHTS COMMISSION

Hearing on Racial and Ethnic Tensions in American Communities: Poverty, Inequality, and Discrimination-Miami

AGENCY: Commission on Civil Rights.

ACTION: Notice of hearing.

SUMMARY: Notice is hereby given pursuant to the provisions of the Civil Rights Commission Amendments of 1994, section 3, Public Law 103–419, 108 Stat. 4338, as amended, and 45 CFR 702.3, that a public hearing of the U.S. Commission on Civil Rights will commence on Thursday, September 14 and 15, 1995, beginning at 8:00 a.m., in the Sandringham/Windsor Conference Room of the Intercontinental Hotel, 100 Chopin Plaza, Miami, Florida 33131.

The purpose of the hearing is to collect information within the jurisdiction of the Commission, under 45 CFR 702.2, related particularly to immigration practices, policies, and perceptions in Miami in order to examine underlying causes of racial and ethnic tensions in the United States.

The Commission is authorized to hold hearings and to issue subpoenas for the production of documents and the attendance of witnesses pursuant to 45 CFR 701.2(c). The Commission is an independent bipartisan, factfinding agency authorized to study, collect, and disseminate information, and to appraise the laws and policies of the Federal Government, and to study and collect information with respect to discrimination or denials of equal protection of the laws under the Constitution because of race, color, religion, sex, age, disability, or national origin, or in the administration of justice.

Hearing impaired persons who will attend the hearing and require the services of a sign language interpreter, should contact Betty Edmiston, Administrative Services and Clearinghouse Division, at (202) 376–8105 (TDD (202) 376–8116), at least five (5) working days before the scheduled date of the hearing.

FOR FURTHER INFORMATION CONTACT: Barbara Brooks, Press and Communications, (202) 376–8312.

Dated: August 8, 1995.

Miguel A. Sapp,

Acting Solicitor.

[FR Doc. 95–19974 Filed 8–11–95; 8:45 am]

BILLING CODE 6335–01–M

DEPARTMENT OF COMMERCE

Coastal Zone Management: Federal Consistency Appeal by Mobil Exploration & Producing U.S. Inc. From an Objection by the State of Florida

AGENCY: National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Notice of decision.

On June 20, 1995, the Secretary of Commerce (Secretary) issued a decision in the consistency appeal of Mobil Exploration & Producing U.S. Inc. (Mobil). Mobil is the operator of Outer Continental Leases OCS–G 10401, 10406, 10407, 10411, and 10412. The lease area, described as Pensacola Area Blocks 845, 846, 889, 890, 933 and 934 (Pensacola Blocks), is located in the northeast Gulf of Mexico Outer Continental Shelf, approximately 10–20 miles from Pensacola, Florida, and approximately 64 miles south-southeast of Theodore, Alabama. The Secretary decided to override the State of Florida's (State) objections to Mobil's Supplemental Plan of Exploration (SPOE).

In 1989, Mobil submitted a proposed Plan of Exploration (POE) to the Minerals Management Service of the Department of the Interior (MMS) together with a certification that the proposed POE was consistent with the State's federally approved Coastal Management Program (CMP), as required under the Coastal Zone Management Act (CZMA), 16 U.S.C. 1451 *et seq.* Mobil proposed drilling six exploratory wells to evaluate the hydrocarbon potential of the Pensacola Area Blocks. MMS approved Mobil's POE and the State concurred with Mobil's consistency certification on April 17, 1990.

Subsequently, on September 6, 1991, Mobil submitted to the MMS a proposed SPOE to drill one additional exploratory well at Pensacola Block 889. The well site is located approximately 74 miles from Theodore, Alabama, and 13.5 miles from Pensacola, Florida. MMS approved Mobil's SPOE subject to the State'a review under the CZMA.

The State objected to Mobil's SPOE, finding the proposal for drilling the additional exploratory well is inconsistent with the State's policies of protecting its marine and coastal resources. Under section 307(c)(3)(B) of the CZMA, and 15 CFR 930.121 and 930.122, the State's objections preclude MMS from issuing a permit or license for Mobil's proposed activity, unless the Secretary finds that the activity is either consistent with the objectives or purposes of the CZMA (Ground I) or necessary in the interest of national security (Ground II). If the requirements of either Ground I or Ground II are met, the Secretary must override the State's objections.

In accordance with section 307(c)(3)(B) of the CZMA, Mobil filed an appeal with the Secretary arguing both Grounds I and II for a Secretarial override. Additionally, three threshold issues were raised by Mobil and the State during the course of the appeal. Upon consideration of the information submitted by Mobil, the State and interested Federal agencies, the Secretary made the findings discussed below.

Regarding the Secretary's findings on the three threshold issues, the decision determined that the State's objections were properly lodged, the Secretary will necessarily determine the adequacy of information for an override rather than summarily dismiss consistency appeals, and the activity before the Secretary on review in this appeal is the one additional exploratory well proposed in Mobil's SPOE.

The Secretary made the following findings with regard to Ground I: Mobil's proposed SPOE activity satisfies the first element of Ground I, because it furthers one of the objectives or purposes of the CZMA. The CZMA recognizes a national objective in achieving a greater degree of energy self-sufficiency. The proposed activity satisfies the second element of Ground I, since the adverse effects of the additional proposed exploratory well on the State's coastal resources and uses will not outweigh the benefit to the national interest.

Mobil's proposed SPOE also satisfies the third element of Ground I, because the activity will not violate the Clean Air Act or the Clean Water Act. Finally, Mobil's proposed SPOE satisfies the fourth element of Ground I, because there is no reasonable alternative

available to Mobil that would allow its proposed activity to be carried out in a manner consistent with the State's CMP.

Regarding Ground II, the decision finds that neither Mobil nor any Federal agency commenting on this ground specifically identified or explained how Mobil's inability to proceed with its proposed SPOE activity would significantly impair a national defense or other national security interest.

Because Mobil's propose SPOE satisfies all four of the requirements of Ground I, the Secretary's decision overrides the State's objections to Mobil's proposal for one additional exploratory well. Consequently, in deciding whether to permit the exploration activity proposed in Mobil's SPOE, MMS is not constrained by the States' objections under the CZMA. Copies of the decision may be obtained from the office listed below.

FOR ADDITIONAL INFORMATION CONTACT: Michael I. Weiss, Attorney-Adviser, Office of the Assistant General Counsel for Ocean Services, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, 1305 East-West Highway, Suite 6110, Silver Spring, Maryland 20910, (301) 713–2967.

Dated: August 7, 1995.

Terry D. Garcia,

General Counsel.

(Federal Domestic Assistance Catalog No. 11.419 Coastal Zone Management Program Assistance.)

[FR Doc. 95–19987 Filed 8–11–95; 8:45 am]

BILLING CODE 3510–08–M

International Trade Administration

[A–351–605]

Notice of Preliminary Results of Antidumping Duty Administrative Review: Frozen Concentrated Orange Juice From Brazil

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: August 14, 1995.

SUMMARY: In response to timely requests for an administrative review by the respondents, Branco Peres Citrus, S.A. (Branco) and CTM Citrus S.A. (CTM), formerly Citropectina, S.A., the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on frozen concentrated orange juice (FCOJ) from Brazil. This review covers two manufacturers/exporters of FCOJ to the United States during the period May 1, 1992, through April 30, 1993. We preliminarily determine the dumping margins for Branco and CTM during this period to be 2.52 and 0.98 percent, respectively. We invite interested parties to comment on these preliminary results.

FOR FURTHER INFORMATION CONTACT: Donna Berg or Greg Thompson, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–0114 or 482–3003, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 5, 1987, the Department published in the **Federal Register** an antidumping duty order on FCOJ from Brazil (52 FR 16426). The Department published in the **Federal Register** on April 28, 1993 a notice of ''Opportunity to Request Administrative Review'' (58 FR 25802) of the antidumping duty order on FCOJ from Brazil for the period of review (POR), May 1, 1992, through April 30, 1993. On May 28, 1993, manufacturers/exporters, Branco and CTM, requested an administrative review for this POR. Branco also submitted a timely request for revocation of the antidumping duty order. The manufacturer/exporter, Frutropic/COINBRA, requested an administrative review for this POR on June 1, 1993. Accordingly, the Department initiated an administrative review on June 25, 1993, (58 FR 34414) with respect to Branco and CTM. On August 24, 1993, (58 FR 44653), we initiated a review with respect to Frutropic/COINBRA.

The Department issued an antidumping questionnaire to Branco, CTM and Frutropic/COINBRA on September 22, 1993. On October 11, 1994, the Department revoked the order with respect to Frutropic/COINBRA in the final results of the administrative review for the 1991 through 1992 POR (59 FR 53137, 53138, October 21, 1994).

Branco and CTM, on November 2 and 24, 1994, respectively, submitted their responses to the Department's questionnaire. On April 14, 1994, the Department issued a supplemental questionnaire to both Branco and CTM. Branco and CTM submitted their responses to these supplemental questionnaires on May 12, 1994.

Verification of the factual information submitted by Branco in this review was conducted on June 22 and 23, 1994.

The Department issued a section D, cost of production/constructed value, questionnaire to Branco and CTM on August 5, 1994, because our preliminary analysis indicated that for certain U.S. sales, contemporaneous third country sales were unavailable for comparison purposes. Branco and CTM submitted comments regarding how foreign market value should be calculated in this review on August 17 and 18, 1994, respectively. (Note: whereas the Department initially believed that section D information was necessary, the Department subsequently revised its determination of the most appropriate methodology to apply in this review. See the ''Foreign Market Value'' section of this notice.)

On September 6, 1994, the Department requested clarification of both Branco's and CTM's responses. Branco and CTM submitted their responses in September 1994. The Department requested further information of both respondents on February 14 and March 15, 1995. Branco and CTM provided this information in March 1995.

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994.

Scope of Review

Imports covered by this review are shipments of FCOJ from Brazil. The merchandise is currently classifiable under item 2009.11.00 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and Customs purposes, our written description of the scope of this review is dispositive.

Fair Value Comparisons

To determine whether sales by Branco and CTM were made at less than fair value (LTFV), we compared the United States price (USP) to the foreign market value (FMV), as specified in the ''United States Price'' and ''Foreign Market Value'' sections of this notice.

United States Price

We based USP on purchase price, in accordance with section 772(b) of the Tariff Act, as amended (1994) (The Act), because all of Branco's and CTM's U.S. sales to the first unrelated purchaser took place prior to importation into the United States and exporter's sales price methodology was not otherwise indicated.

We calculated purchase price based on packed FOB prices to unrelated customers in the United States. We

made deductions, where appropriate, for foreign inland freight and Brazilian port charges.

Foreign Market Value

In order to determine whether there were sufficient sales of FCOJ in the home market to serve as a viable basis for calculating FMV, we compared each respondents' volume of home market sales of FCOJ to the volume of third country sales in accordance with section 773(a)(1)(B) of the Act. We found that the home market was not viable for either of the respondents. Based on each respondent's questionnaire response, we selected the Netherlands and Germany as the appropriate third country markets for Branco and CTM, respectively, in accordance with 19 CFR 353.49(b) (see November 2, 1993, submission (page three and exhibit B) and November 24, 1993, submission (page four)).

In accordance with 19 CFR 353.49(a)(1), we calculated FMV for both respondents based on third country FOB sales or offers for sale. If a contemporaneous third country sale was available, we based FMV on the third country sale. Where contemporaneous third country sales were not available, we based FMV on the applicable minimum export price [1] as a third country offer for sale. (*See* Preliminary Results Concurrence Memorandum, dated June 27, 1995.) We made deductions, where appropriate, for foreign inland freight, port charges and storage. In accordance with section 773(a)(1) of the Act, we deducted, as appropriate, third country packing costs and added U.S. packing costs (packing costs were not incurred on bulk sales). We made circumstance-of-sale adjustments, where appropriate, for differences in commission and credit expenses. The values used for these adjustments varied depending on whether an actual third country sale or third country offer for sale was used. For actual third country sales, we used the reported transaction-specific amounts. For third country offers for sale, we relied on weighted-average POR values of reported third-country charges.

Since Branco's and CTM's prices are linked to the minimum export price, we used FMV periods shorter than a month (see Preliminary Results Concurrence Memorandum, dated June 27, 1995). These shorter periods were used because the price volatility of minimum export prices within POR months was significant enough to have artificially increased or decreased dumping margins (*see Frozen Concentrated Orange Juice from Brazil: Final Results of Antidumping Duty Administrative Review and Revocation of Order in Part*, (59 FR 53137, October 21, 1994)). Periods were created based on a change in the minimum export price throughout the continuum of the POR (*see* Preliminary Results Concurrence Memorandum, dated June 27, 1995).

Preliminary Results of the Review

As a result of this review, we preliminarily determine the dumping margins to be:

Manufacturer/ exporter	Time period	Margin (percent)
Branco	5/1/92–4/30/93	2.52
CTM	5/1/92–4/30/93	0.98

Individual differences between USP and FMV may vary from the percentages stated above. Upon completion of this administrative review, the Department will issue appraisement instructions directly to the U.S. Customs Service.

Furthermore, the following deposit requirements will be effective for all shipments of FCOJ entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(1) of the Act: (1) The cash deposit rate for the reviewed company will be that established in the final results of this administrative review; (2) for previously reviewed or investigated companies not listed above, 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 prior review, or the original LTFV investigation, but the manufacturer is such a firm, the cash deposit rate will be the rate established for the most recent period for the manufacturer of FCOJ.

On May 25, 1993, the Court of International Trade (CIT) in *Floral Trade Council* v. *United States*, Slip Op. 93–79, and *Federal-Mogul Corporation* v. *United States*, Slip Op. 93–83, decided that once an ''all others'' rate is established for a company, it can only be changed through an administrative review. The Department has determined that in order to implement these decisions, it is appropriate to reinstate the original ''all others'' rate from the LTFV investigation (or that rate as amended for correction of clerical errors or as a result of litigation) in proceedings governed by antidumping duty orders for the purposes of establishing cash deposits in all current and future administrative reviews. Because this proceeding is governed by an antidumping duty order, the ''all others'' rate for the purposes of this review will be 1.96 percent *ad valorem*, the ''all others'' rate established in the LTFV investigation (52 FR 8324, March 17, 1987).

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Public Comment

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room B–099, within ten days of publication. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed.

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary no later than August 25, 1995, and rebuttal briefs no later than August 29, 1995. A public hearing, if requested, will be held on August 31, 1995, at 10:00 am at the U.S. Department of Commerce, in Room 1851, 14th Street and Constitution Avenue, NW, Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours prior to the scheduled time. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs. The Department will publish a notice of final results of this administrative review, including an analysis of issues raised in any written comments.

This result is published pursuant to section 751(a)(1) of the Act and 19 CFR 353.22.

[1] The minimum export price is a floor price set by the Carteira do Comércio Exterior do Banco do Brasil (CACEX), the export department of the Bank of Brazil. Minimum export prices are based on the price of FCOJ on the New York Cotton Exchange. Because the price movements of FCOJ on the futures market are irregular, the minimum export price may remain the same or change several times within a month. It should be noted that during the POR of this sixth review, both Branco and CTM sold FCOJ at the minimum export price.

Dated: August 8, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–20025 Filed 8–11–95; 8:45 am]

BILLING CODE 3510–DS–P

[A–412–803]

Industrial Nitrocellulose From the United Kingdom; Amendment of Final Results of Antidumping Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of amendment of final results of Antidumping Duty Administrative Review.

SUMMARY: We are amending our final results of administrative review of the antidumping duty order on industrial nitrocellulose (INC) from the United Kingdom published on December 28, 1994, to reflect the correction of a ministerial error made in the margin calculation in those final results. We are publishing this amendment to the final results in accordance with 19 CFR 353.28(c).

EFFECTIVE DATE: August 14, 1995.

FOR FURTHER INFORMATION CONTACT: Rebecca Trainor or Maureen Flannery of the Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington D.C. 20230; telephone (202) 482–4733.

SUPPLEMENTARY INFORMATION:

Background

The review covers one exporter, Imperial Chemical Industries PLC, and the period July 1, 1992 through June 30, 1993. The Department of Commerce (the Department) published the preliminary results on May 12, 1994 (59 FR 24684), and the final results on December 28, 1994 (59 FR 66902).

Scope of Review

This review covers shipments of INC from the United Kingdom. INC is a dry, white, amorphous synthetic chemical with a nitrogen content between 10.8 and 12.2 percent, which is produced from the reaction of cellulose with nitric acid. It is used as a film-former in coatings, lacquers, furniture finishes, and printing inks. INC is currently classifiable under Harmonized Tariff Schedule (HTS) item number 3912.20.00. The HTS subheading is provided for convenience and U.S. Customs Service purposes. The written description remains dispositive. The scope of the antidumping order does not include explosive grade nitrocellulose, which has a nitrogen content of greater than 12.2 percent.

Amended Final Results

On January 4, 1995, the petitioner, the Aqualon Company, alleged that the Department had committed a ministerial error in calculating the final anitdumping duty margin. The petitioner alleged that the Department had double-counted the home market commission offset. We have reviewed this allegation, and agree with petitioner. We have therefore amended our final results for this ministerial error.

Final Results of Review

Upon review of the allegation submitted, the Department has determined that the following margin exists for the period July 1, 1992 through June 30, 1993:

Manufacturer/exporter	Time period	Margin (percent)
Imperial Chemicals Industries PLC	7/1/92–6/30/93	6.62

The Customs Service shall assess antidumping duties on all appropriate entries. Individual differences between U.S. price and foreign market value may vary from the percentage stated above. The Department will issue appraisement instructions directly to the Customs Service.

Furthermore, the following deposit requirements will be effective upon publication of this notice of amended final results of review for all shipments of INC from the United Kingdom entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(1) of the Tariff Act of 1930, as amended: (1) The cash deposit rate for the reviewed company will be the rate listed above; (2) for previously reviewed or investigated companies not listed above, 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 or a previous review or the less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established in the LTFV investigation for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will be the ''all others'' rate of 11.13 percent established in the final notice of the LTFV investigation.

Unless otherwise stated, all citations to the statutes and to the Department's regulations are references to the provisions as they existed on December 31, 1994. This administrative review and notice are in accordance with section 751(f) of the Act (19 U.S.C. 1673(d)) and section 353.28(c) of the Department's regulations.

Dated: August 4, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–20029 Filed 8–11–95; 8:45 am]

BILLING CODE 3510–DS–P

[A–351–505]

Certain Malleable Cast Iron Pipe Fittings From Brazil; Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results of antidumping duty administrative review.

SUMMARY: On February 22, 1995, the Department of Commerce (the Department) published the preliminary results of its administrative review of the antidumping duty order on certain malleable cast iron pipe fittings from Brazil. This review covers Industria de Fundicao Tupy S.A. (Tupy), a manufacturer and exporter of this merchandise to the United States, and the period May 1, 1993 through April 30, 1994. The firm failed to submit a response to our questionnaire. As a result, we determined to use the best information otherwise available (BIA) for cash deposit and assessment purposes.

We gave interested parties an opportunity to comment on the preliminary results. Based on our analysis of the comments received, we have made certain changes for the final results.

EFFECTIVE DATE: August 14, 1995.

FOR FURTHER INFORMATION CONTACT: Thomas E. Schauer or Richard Rimlinger, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone (202) 482–4852/4477.

SUPPLEMENTARY INFORMATION:

Background

On May 4, 1994, the Department published in the **Federal Register** (59

FR 23051) a notice of ''Opportunity to Request an Administrative Review'' of the antidumping duty order on certain malleable cast iron pipe fittings from Brazil. On May 4, 1994, we received from the petitioners in this case, Grinnell Corporation, Ward Manufacturing Inc., and Stockham Valves and Fittings Co., a request to initiate an administrative review of Tupy, a manufacturer and exporter of this merchandise to the United States. On July 15, 1994, in accordance with 19 CFR 353.22(c), we initiated an administrative review of this order for Tupy covering the period May 1, 1993 through April 30, 1994 (see 59 FR 36160). On February 22, 1995, we published the preliminary results of this administrative review (*see* 60 FR 9821).

The Department conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Tariff Act).

Unless otherwise indicated, all citations to the statute and to the Department's regulations are references to the provisions as they existed on December 31, 1994.

Scope of Review

Imports covered by this review are shipments of certain malleable cast iron pipe fittings, other than grooved, from Brazil. In the original order, these products were classifiable in the Tariff Schedules of the United States, Annotated, under item numbers 610.7000 and 610.7400. These products are currently classifiable under item numbers 7307.19.00 and 7307.19.90 of the Harmonized Tariff Schedule (HTS). The HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive.

Best Information Available

In accordance with section 776(c) of the Tariff Act, we have determined that the use of BIA is appropriate for Tupy. Our regulations provide that we may take into account whether a party refuses to provide information (19 CFR 353.37(b)) in selecting BIA. Generally, whenever a company refuses to cooperate with the Department or otherwise significantly impedes the proceeding, as Tupy did here, the Department uses as BIA the highest rate for any company for the same class or kind of merchandise from the current or any prior segment of the proceeding. When a company substantially cooperates with our requests for information, but fails to provide all the information requested in a timely manner or in the form requested, we use as BIA the higher of (1) the highest rate (including the ''all others'' rate) ever applicable to the firm for the same class or kind of merchandise from the same country from either the less-than-fair-value (LTFV) investigation or a prior administrative review; or (2) the highest calculated rate in the review for any firm for the same class or kind of merchandise from the same country. *See Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From the Federal Republic of Germany, et al.; Final Results of Antidumping Duty Administrative Review*, 57 FR 28360, 28379 (June 24, 1992); *see* also *Allied-Signal Aerospace Co. v. United States*, 996 F.2d 1185 (Fed. Cir. 1993). In our preliminary results of review, we preliminarily applied to Tupy, as first-tier BIA, a rate of 5.64 percent, which was the rate we determined in the LTFV investigation.

Upon review of the comments our choice of a rate to use as first-tier BIA has changed. In this case, Tupy is the only company to have ever been reviewed or investigated, and we have only calculated one margin, which was in the less-than-fair-value (LTFV) investigation. Due to the unusual situation, we have determined to use as BIA the simple average of the rates from the petition. See our response to Comment, below. The rate we have calculated for Tupy is 34.64 percent.

General Issues Raised By the Petitioner

Comment: Petitioner contends that the Department's use of its standard BIA practice for the preliminary results of this review is inappropriate. Petitioner points out that this resulted in no change in the margin applicable to respondent. Petitioner argues that this rewards respondent for being uncooperative with the Department's information requests.

Petitioner also argues that, since Tupy is the sole respondent in this case, under the Department's regular practice, Tupy's margin would never change in an administrative review so long as it does not respond to the Department's requests for information. Thus, Tupy would be able to dump at will without fear of repercussion unless the Department alters its choice of BIA for this case. Petitioner argues that the Department is not limited to the standards enunciated in *Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From the Federal Republic of Germany, et al.; Final Results of Antidumping Duty Administrative Review*, 56 FR 31692, 31704 (July 11, 1991). Rather, petitioner states, the Department has the authority to choose other BIA when the circumstances warrant it, citing *Krupp Stahl, A.G. v. United States*, 822 F. Supp. 789 (CIT 1993) (*Krupp Stahl*) in support of its arguments.

Petitioner suggests that the Department use as BIA the simple average of the margins alleged in the petition. Petitioner also suggests, as an alternative methodology, that the Department should adjust the original margin for appreciation of Brazil's currency against the dollar since the period of the original LTFV investigation. Citing reports from the International Trade Commission (ITC) submitted as an attachment to its case brief, petitioner argues that the Brazilian cruzeiro has appreciated against the dollar between the period of investigation and the current period of review by 33.2 percent, and that the Department should assume that Brazilian foreign market values have increased similarly. Petitioner states that there is precedent for this approach in *Malleable Iron Pipe Fittings, Other than Grooved, from Korea; Preliminary Results of Administrative Review*, 54 FR 7577 (Feb. 22, 1989), in *Malleable Iron Pipe Fittings, Other than Grooved, from Korea; Final Results of Administrative Review*, 54 FR 13090 (Mar. 30, 1989), and in *Malleable Iron Pipe Fittings, Other than Grooved, from Taiwan; Preliminary Results of Administrative Review*, 54 FR 38713 (Sept. 20, 1989).

Respondent argues that the Department applied BIA correctly in the preliminary results, and that petitioner misrepresents the decision in *Krupp Stahl*. Respondent contends that, while *Krupp Stahl* allowed the Department to use a preliminary margin from the LTFV investigation, which adopted the petition rates, the court did not hold that a margin alleged in a petition can be used over a published margin for a particular company.

Respondent also argues that the courts have held, in *Rhone Poulenc, Inc. v. United States*, 899 F.2d 1185, 1191 (1990), that the purpose of BIA is ''to determine current margins as accurately as possible'', and that the Department may not use BIA in a punitive manner. Respondent claims that using rates from the petition would be less accurate than using the rates calculated by the Department in the LTFV investigation.

Respondent argues that the methodology suggested by petitioner for adjusting the margin for changes in currency values would result in an inaccurate margin because the rates used in the ITC report cited in petitioner's case brief use real exchange rates instead of nominal exchange rates. Respondent argues that petitioner has not provided any compelling argument

why real exchange rates should be used instead of nominal exchange rates.

Respondent also states that, in the precedent cited by petitioner, the Department assumed that prices in the United States and the foreign market remained constant. Respondent alleges that prices have not been constant in the United States, and, therefore, such an assumption cannot be made in this case.

Department's Position: We agree with petitioner. Tupy was the only company investigated in the antidumping duty LTFV investigation on malleable cast iron pipe fittings from Brazil. Because this is the first administrative review of this order, Tupy's final LTFV rate of 5.64 percent is the only rate for any company from any segment of the proceeding. If we were to follow our regular practice for assigning uncooperative BIA rates, Tupy would benefit by receiving its own LTFV rate in this and any subsequent review in which it chooses not to respond to our requests for information. This is contrary to the Department's aim in using BIA. As the Court of Appeals for the Federal Circuit has affirmed, ''the ITA may use BIA as an investigative tool, which [ITA] may wield as an informal club over recalcitrant parties or persons'' to induce cooperation with our requests for information. *See Rhone Poulenc, Inc. v. United States,* 899 F.2d 1185 at 1191 (1990) (*Rhone Poulenc II*). Therefore, we find that there is justification in this case to depart from past Department practice in determining uncooperative BIA.

By refusing to provide a questionnaire response, as indicated in its letter to the Department dated October 31, 1994, Tupy leaves unanswered a legitimate question as to whether the firm dumped subject merchandise during the period of review to a greater or lesser extent than in the past. In not responding to our requests for information, Tupy could be relying upon our normal BIA practice to lock in a rate that is capped at its LTFV rate. Such a capped BIA rate would allow Tupy to practice injurious price discrimination to a greater degree than at the time of the LTFV investigation without fear of adverse consequences. With such a capped rate, Tupy would no longer have an incentive to participate in an administrative review which would determine the extent to which Tupy is actually dumping subject merchandise in the United States.

In *Rhone Poulenc, Inc. v. United States,* 710 F. Supp. 341 (*Rhone Poulenc I*) at 347, the Court of International Trade (CIT) ruled that a respondent should not be allowed to control the results of the review by providing partial information (or, as in this case, no information) or otherwise hindering the review. Citing *Rhone Poulenc I,* the CIT has also determined that ''to use the rate demanded by [the respondent] might have the effect of 'plac[ing] control of the investigation in the hands of uncooperative respondents who could force Commerce to use possibly unrepresentative information most beneficial for them.' '' *See Krupp Stahl,* 822 F. Supp. at 793. Contrary to Tupy's claim that the function of BIA is solely to find the most accurate rate possible, in *Krupp Stahl,* the CIT characterizes one of the functions of BIA as ''cooperation-inducing.'' *Id.*

We also find incorrect Tupy's assertion that the *Krupp Stahl* decision upholds only the authority to use a preliminary margin based on petition rates as BIA, and not the authority to use the petition rates themselves. Respondent correctly states that, in *Krupp Stahl,* the petition-based information used as BIA was derived from the LTFV preliminary investigation. *See* 822 F. Supp. at 796. Resort to the preliminary determination for evidence of petition-based BIA was necessary in that case because the petition was not on the administrative record of the review under consideration in *Krupp Stahl,* and each administrative determination must be supported by sufficient evidence on the record. *See* 822 F. Supp. at 795. Contrary to Tupy's assertion, the CIT's decision in *Krupp Stahl* did not limit the use of petition-based information in administrative reviews to cases where margins in the preliminary determinations were petition-based. Rather, in *Krupp Stahl,* the CIT upheld our interpretation that the use of petition-based information as BIA in an administrative review was not contrary to the statute, and that it did not ''contravene any clearly discernable legislative intent.'' *See Krupp Stahl,* 822 F. Supp. at 794. Because Tupy has failed to cooperate in this administrative review, and a BIA rate capped at Tupy's LTFV rate would not induce Tupy's cooperation in this or any future review, we have determined that it is appropriate to use petition-based information as BIA in this administrative review.

We have also determined that the use of petition-based information as BIA is more appropriate than adjusting the LTFV rate for currency appreciation. Though the latter methodology may be appropriate in other circumstances, in this case we have rates from the petition, which, after correction, were found to be acceptable by the Department as a basis for initiating the LTFV investigation. Further, there is limited record evidence available for determining an adjustment to the LTFV margin for currency fluctuations, including whether we should use real or nominal exchange rates for such a calculation. Thus, we conclude that the use of petition-based rates for BIA is a better approach in this administrative review.

In order to use petition-based information as BIA for Tupy in this administrative review, the Department must include the petition in the administrative record of this review. Therefore, with the permission of petitioner, and pursuant to our regulations at 19 CFR 353.3, we have obtained a copy of the petition from the administrative record of the LTFV investigation, and included it in the record of this administrative review.

We have determined that the simple average of the rates from the petition is a more appropriate standard for BIA in this case. The petition rates, as adjusted by the Department for the LTFV initiation notice, are 8.8, 14.46, 53.6, and 61.7 percent. *See Malleable Cast Iron Pipe Fittings From Brazil; Initiation of Antidumping Duty Investigation,* 50 FR 34730. The simple average of these rates is 34.64 percent.

Final Results of Review

We determine the margin for this administrative review to be:

Producer/exporter	Margin
Industria de Fundicao Tupy S.A	34.64

The Department will instruct the Customs Service to assess antidumping duties on all appropriate entries. Furthermore, the following deposit requirements will be effective upon publication of these final results of administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse for consumption, as provided by section 751(a)(1) of the Act: (1) The cash deposit rate for the reviewed company will be the rate listed above; (2) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value 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; and (3) the cash deposit rate for all other manufacturers or exporters will be the ''all others'' rate of 5.64 percent. This is the rate established during the LTFV investigation.

These deposit requirements shall remain in effect until publication of the

final results of the next administrative review.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 353.34(d). Failure to comply is a violation of the APO.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and 19 CFR 353.22, 353.25.

Dated: August 7, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–20030 Filed 8–11–95; 8:45 am]

BILLING CODE 3510–DS–P

Export Trade Certificate of Review

ACTION: Notice of issuance of an amended Export Trade Certificate of Review, Application No. 90–4A006.

SUMMARY: On June 26, 1995, the Department of Commerce issued an amendment to the Export Trade Certificate of Review granted to the Forging Industry Association (''FIA''). Notice of the original Certificate was published in the **Federal Register** on July 9, 1990 (55 FR 28801, July 13, 1990).

FOR FURTHER INFORMATION CONTACT: W. Dawn Busby, Director, Office of Export Trading Company Affairs, International Trade Administration, (202) 482–5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. Sections 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. The regulations implementing Title III are found at 15 CFR Part 325 (1993).

The Office of Export Trading Company Affairs is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Department of Commerce to publish a summary of a Certificate in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Amended Certificate

The Forging Industry Association's (''FIA'') original Certificate was issued on July 9, 1990 (55 FR 28801, July 13, 1990). Previous amendments to the Certificate were issued on April 30, 1991 (56 FR 21128, May 7, 1991), May 29, 1992 (57 FR 24022, June 5, 1992) and on April 1, 1994 (59 FR 16619, April 7, 1994).

The Amendment

1. Added the following company as a ''Member'' within the meaning of Section 325.2(1) of the Regulations (15 CFR 325.2(1)): National Forge Company, Irvine, Pennsylvania;

2. Deleted the following six companies as ''Members'' within the meaning of Section 325.2(1) of the Regulations (15 CFR 325.2(1)): Columus McKinnon Corporation, Amherst, New York; Cooper tools-Brewer-Tichener/Merrill, Cortland, New York; Kervick Enterprises, Inc, Worcester, Massachusetts; FMC Corporation, Anniston, Alabama; McWilliams Forge Company, Inc., Rockaway, New Jersey; and Union Forging Co., Endicott, New York.

3. Reflected that Cameron Forge Company, Cypress, Texas is now a division of Wyman-Gordon Company, Worcester, Massachusetts. Since Wyman-Gordon Company is a current member, Cameron Forge Company was deleted as a ''Member''.

4. Reflected a change in the names of the following current Members: Airfoil Forging Textron, Inc., Cleveland, Ohio is now Turbine Engine Components, Textron (a subsidiary of Textron, Inc.).

A copy of the amended certificate will be kept in the International Trade Administration's Freedom of Information Records Inspection Facility, Room 4102, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230.

Dated: August 8, 1995.

W. Dawn Busby,

Director, Office of Export Trading Company Affairs.

[FR Doc. 95–19976 Filed 8–11–95; 8:45 am]

BILLING CODE 3510–D–R–P

Export Trade Certificate of Review

ACTION: Notice of Issuance of an amended Export Trade Certificate of Review, Application No. 95–5A007.

SUMMARY: On August 3, 1995, the Department of Commerce issued an amendment to the Export Trade Certificate of Review granted to the U.S. Surimi Commission (''USSC''). Notice of the original Certificate was published in the **Federal Register** on August 22, 1990 (55 FR 35445).

FOR FURTHER INFORMATION CONTACT: W. Dawn Busby, Director, Office of Export Trading Company Affairs, International Trade Administration, (202) 482–5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. Sections 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. The regulations implementing Title III are found at 15 CFR Part 325 (1993).

The Office of Export Trading Company Affairs is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Department of Commerce to publish a summary of a Certificate in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Amended Certificate

The U.S. Surimi Commission's (''USSC'') original Certificate was issued on August 22, 1990 (55 FR 35445, August 30, 1990). Previous amendments to the Certificate were issued on December 12, 1990 (55 FR 53031, December 26, 1990); June 11, 1991 (56 FR 27946, June 18, 1991); May 22, 1992 (57 FR 23078, June 1, 1992); and August 12, 1993 (58 FR 44504 August 23, 1993).

The Amendment

1. Added the following companies as ''Members'' within the meaning of Section 325.2(1) of the Regulations (15 CFR 325.2(1)): Alaska Trawl Fisheries, Inc., Edmonds, Washington (controlling entity: Daerim Corporation, Seoul, Korea); and Emerald Seafoods, N.W., Limited Partnership.

2. Deleted three companies as ''Members'' within the meaning of Section 325.2(1) of the Regulations (15 CFT 325.2(1)): Pacific Orion Seafoods, Inc., Arctic Alaska Seafoods, Inc., and Golden Alaska Seafoods, Inc.

3. Added the following product to Export Trade as defined by Section 325.2(j) of the Regulations: white fish meal.

A copy of the amended certificate will be kept in the International Trade Administration's Freedom of Information Records Inspection Facility, Room 4102, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230.

Dated: August 8, 1995.

W. Dawn Busby,

Director, Office of Export Trading Company Affairs.

[FR Doc. 95–19977 Filed 8–11–95; 8:45 am]

BILLING CODE 3510–D–R–P

National Oceanic and Atmospheric Administration

[I.D. 080795A]

North Pacific Fishery Management Council; Plan Team Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of meetings.

SUMMARY: The North Pacific Fishery Management Council's Gulf of Alaska (GOA) and Bering Sea/Aleutian Islands (BSAI) plan teams will hold meetings.

DATES: The meetings will begin at 1:00 p.m. on September 5, 1995, and continue until 5:00 p.m. on September 8, 1995.

ADDRESSES: The meetings will be held at the Alaska Fisheries Science Center, 7600 Sand Point Way NE., Room 2079, Building 4, Seattle, WA.

Council address: North Pacific Fishery Management Council, P.O. Box 103136, Anchorage, AK 99510.

FOR FURTHER INFORMATION CONTACT: Dave Witherell or Jane DiCosimo; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: The agenda for the meetings will include the following subjects:

1. Review available stock assessments and catch statistics and prepare preliminary stock assessment documents for the 1996 groundfish fisheries in the Gulf of Alaska and Bering Sea/Aleutian Islands.

2. Review proposals for amendments to the groundfish fishery management plans for the GOA and BSAI.

3. Review research needs and priorities.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Helen Allen, 907–271–2809, at least 5 working days prior to the meeting date.

Dated: August 8, 1995.

Richard W. Surdi,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 95–20032 Filed 8–11–95; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 073195C]

South Atlantic Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold public meetings of its Golden Crab, Controlled Access and Snapper Grouper Committees and its Golden Crab Advisory Panel (GCAP); and a Council session. Also, a joint meeting of the South Atlantic and Gulf of Mexico Councils' mackerel committees will be held.

DATES: The meetings will be held from August 21 to August 25, 1995, See **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES: The meetings will be held at the Town and Country Inn, 2008 Savannah Highway, Charleston, SC 29407; telephone: (803) 571–1000.

Council address: South Atlantic Fishery Management Council; One Southpark Circle, Suite 306; Charleston, SC 29407–4699.

FOR FURTHER INFORMATION CONTACT: Robert K. Mahood (Council staff); telephone: (803) 571–4366; fax: (803) 769–4520.

SUPPLEMENTARY INFORMATION: The meeting dates are as follows:

August 21, 1995, 8:30 a.m. to 12:00 noon—Golden Crab AP meeting;

August 21, 1995, 1:30 p.m. to 5:00 p.m.—Joint meeting of the GCAP and the Golden Crab Committee;

August 22, 1995, 8:30 a.m. to 10:00 a.m.—Golden Crab Committee;

August 22, 1995, 10:00 a.m. to 12:00 noon—Controlled Access Committee;

August 22, 1995, 1:30 p.m. to 5:00 p.m.—Joint South Atlantic and Gulf Mackerel Committees;

August 23, 1995, 8:30 a.m. to 12:00 noon—Joint South Atlantic and Gulf Mackerel Committees;

August 23, 1995, 1:30 p.m. to 5:00 p.m.—Snapper Grouper Committee;

August 24, 1995, 8:30 a.m. to 10:30 a.m.—Snapper Grouper Committee;

August 24, 1995, 11:00 a.m. to 5:30 p.m.— Council session;

August 25, 1995, 8:30 a.m. to 12:30 p.m.— Council session;

The GCAP will meet to develop recommendations on the fishery management plan (FMP) for golden crab. The GCAP then will meet jointly with the Golden Crab Committee to review public hearing and NMFS informal review comments. At that time, the GCAP will make its recommendations as to management measures that should be included in the FMP and discuss the rationale for its recommendations with the committee members. The Golden Crab Committee will meet to develop its final recommendations for Council action. Management options being considered for the Golden Crab FMP can be obtained by contacting the Council office directly (see **ADDRESSES**).

The Controlled Access Committee will review options being considered for Amendment 9 to the Snapper Grouper FMP. These options address limiting entry in the deep water fishery for snowy grouper and tile fish and possibly other segments of the snapper grouper fishery. The committee will recommend to the Council which options to take to public hearing.

The joint South Atlantic and Gulf Mackerel Committees will discuss a range of options to be included in Amendment 8 to the Coastal migratory Pelagics (Mackerel) FMP. They will recommend to both Councils options to take to public hearing. Amendments to this FMP must be approved by both Councils.

The Snapper Grouper Committee will receive a report on a reef fish economic survey and the 1994–95 wreckfish fishery. It will review management options for Amendment 8 to the FMP and recommend to the Council which options to take to public hearing.

The full Council will convene and receive reports from the Golden Crab, Shrimp Controlled Access, Snapper Grouper and Mackerel Committees. The Council will take final action on the Golden Crab FMP for formal submission to the Secretary of Commerce. The Council will also select the options to take to public hearing for Shrimp FMP Amendment 2, Snapper Grouper FMP Amendments 8 and 9, and Coastal Migratory Pelagics (Mackerel) FMP Amendment 9. The Council will hear a

report from its Habitat and Environmental Protection Advisory Panel and additional reports on the status of the Magnuson Fishery Conservation and Management Act amendments and reauthorization, the Council Chairmen's meeting and state and agency liaison activities.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) by August 14, 1995.

Dated: August 7, 1995.

Richard W. Surdi,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 95–19959 Filed 8–11–95; 8:45 am]

BILLING CODE 3510–22–M

[I.D. 073195E]

Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Issuance of modification to permit no. 738 (P77#51).

SUMMARY: Notice is hereby given that on July 31, 1995, permit no. 738, issued to Southeast Fisheries Science Center, NMFS, NOAA, 75 Virginia Beach Drive, Miami, FL 33149, was modified.

ADDRESSES: The modification and related documents are available for review upon written request or by appointment in the following offices:

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713–2289); and

Southeast Region, NMFS, 9721 Executive Center Drive, St. Petersburg, FL 33702–2532.

SUPPLEMENTARY INFORMATION: The subject modification has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the provisions of §§ 216.33(d) and (e) of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the provisions of § 222.25 of the Regulations Governing the Taking, Importing, and Exporting of Endangered Fish and Wildlife (50 CFR part 222).

Section A.1.g. is added to extend the validity of the permit until December 31, 1996.

Dated: July 31, 1995.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 95–19960 Filed 8–11–95; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 080295C]

Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Receipt of application for a public display permit (PHF182).

SUMMARY: Notice is hereby given that the Oregon Coast Aquarium, 2820 SE. Ferry Slip Road, Newport, OR 97365, has applied in due form for a public display permit.

DATES: Written comments must be received on or before September 13, 1995.

ADDRESSES: The application and related documents are available for review upon written request or by appointment in the following offices:

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910, (301/713–2289); and

Director, Northwest Region, NMFS, 7600 Sand Point Way, NE, BIN C15700, Seattle, WA 98115 (206/526–6150).

Written data or views, or requests for a public hearing on this application should be submitted to the Chief, Permits Division, F/PR1, Office of Protected Resources, 1315 East-West Highway, Silver Spring, MD 20910, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular application would be appropriate. The holding of such a hearing is at the discretion of the Director, Office of Protected Resources.

Concurrent with the publication of this notice in the **Federal Register**, copies of this application are being forwarded to the Marine Mammal Commission and its Committee of Scientific Advisors.

SUPPLEMENTARY INFORMATION: The subject permit is requested to import for public display purposes one adult male killer whale (*Orcinus orca*), from the Reino Aventura theme park, Mexico City, Mexico, under the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361 *et seq.*), and the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216).

The Oregon Coast Aquarium holds an Exhibitor's License (No. 92C–057) under the Animal Welfare Act; is open to the public on a regularly scheduled basis with access that is not limited or restricted other than by charging an admission fee; and offers an educational program based in part upon the educational standards of the American Zoo and Aquarium Association.

Dated: August 3, 1995.

Ann D. Terbush,

Chief, Division of Permits & Documentation, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 95–19973 Filed 8–11–95; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the Defense Environmental Response Task Force

AGENCY: Office of the Deputy Under Secretary of Defense (Environmental Security).

ACTION: Notice of business meeting and hearing.

SUMMARY: Pursuant to Public Law 92–463, notice is hereby given of a business meeting and hearing of the Defense Environmental Response Task Force (DERTF). The DERTF is charged with studying and providing findings and recommendations on environmental restoration at military installations being closed or realigned. The purpose of the meeting is to develop the fiscal year (FY) 1995 report to Congress. The DERTF will hear presentations from the Future Land Use Working Group, the Fast-Track Cleanup Implementation Working Group, the Ft. Devans Base Realignment and Closure Cleanup Team and the Local Redevelopment Authority. The business meeting and hearing will be open to the public. Public witnesses desiring to speak before the DERTF should contact Shah A. Choudhury, Executive Secretary, and prepare a written statement that can be summarized orally before the DERTF at the time to be fixed for public witnesses. Written statements must be received by the close of business on September 6, 1995, at the Office of the Deputy Under Secretary of Defense (Environmental Security.)

DATES: September 19, 1995—9:15 a.m.–2:30 p.m.; September 20, 1995—9:15 a.m.–8:00 p.m.; September 21, 1995—9:15 a.m.–5:00 p.m.

PUBLIC COMMENT PERIODS ARE: September 20, 1995—7:00 p.m.–8:00

p.m.; September 21, 1995—12:00 p.m.–1:00 p.m.

FOR FURTHER INFORMATION CONTACT:

Mr. Shah A. Choudhury, Executive Secretary, Office of the Deputy Under Secretary of Defense (Environmental Security), 3400 Defense Pentagon, Washington, DC 20301–3400; telephone (703) 697–7475.

Dated: August 8, 1995.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer Department of Defense.

[FR Doc. 95–19999 Filed 8–11–95; 8:45 am]

BILLING CODE 5000–04–M

Defense Partnership Council Meeting

AGENCY: Department of Defense.

ACTION: Notice of meeting.

SUMMARY: The Department of Defense (DoD) announces a meeting of the Defense Partnership Council. Notice of this meeting is required under the Federal Advisory Committee Act. This meeting is open to the public. The topics to be covered are partnership successes within DoD and action items related to the Defense Partnership Council Plan of Action.

DATES: The meeting is to be held Wednesday, September 6, 1995, in room 1E801, Conference Room 7, the Pentagon, from 1:00 p.m. until 3:00 p.m. Comments should be received by September 1, 1995, in order to be considered at the September 6 meeting.

ADDRESSES: We invite interested persons and organizations to submit written comments or recommendations. Mail or deliver your comments or recommendations to Mr. Kenneth Oprisko at the address shown below. Seating is limited and available on a first-come, first-served basis. Individuals wishing to attend who do not possess an appropriate Pentagon building pass should call the below listed telephone number to obtain instructions for entry into the Pentagon. Handicapped individuals wishing to attend should also call the below listed telephone number to obtain appropriate accommodations.

FOR FURTHER INFORMATION CONTACT:

Mr. Kenneth Oprisko, Chief, Labor Relations Branch, Field Advisory Services Division, Defense Civilian Personnel Management Service, 1400 Key Blvd, Suite B–200, Arlington, VA 22209–5144, (703) 696–6301, ext. 704.

Dated: August 8, 1995.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 95–20001 Filed 8–11–95; 8:45 am]

BILLING CODE 5000–04–M

Defense Science Board Task Force on Readiness, Phase II

ACTION: Notice of Advisory Committee Meetings.

SUMMARY: The Defense Science Board Task Force on Readiness, Phase II will meet in closed session on August 23, 1995 at the Pentagon, Arlington, Virginia. In order for the Task Force to obtain time sensitive classified briefings, critical to the understanding of the issues, this meeting is scheduled on short notice.

The mission of the Defense Science Board is to advise the Secretary of Defense through the Under Secretary of Defense (Acquisition and Technology) on scientific and technical matters as they affect the perceived needs of the Department of Defense. At this meeting the Task Force will provide advice, recommendations, and supporting rationale on the components of a Readiness Early Warning System to insure that our forces do not become ''hollow,'' and, where deficiencies may begin to emerge, to suggest corrective actions.

In accordance with Section 10(d) of the Federal Advisory Committee Act, P.L. No. 92–463, as amended (5 U.S.C. App. II, (1988)), it has been determined that this DSB Task Force meeting, concerns matters listed in 5 U.S.C. § 552b(c)(1) (1988), and that accordingly this meeting will be closed to the public.

Dated: August 8, 1995.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer Department of Defense.

[FR Doc. 95–20000 Filed 8–11–95; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF EDUCATION

[CFDA Nos.: 84.116A; 84.116B]

Fund for the Improvement of Postsecondary Education—Comprehensive Program (Preapplication and Applications); Notice Inviting Applications for New Awards for Fiscal Year (FY) 1996

Purpose of Program: To provide grants or enter into cooperative agreements to improve postsecondary education opportunities.

Eligible Applicants: Institutions of higher education or combinations of such institutions and other public and private nonprofit educational institutions and agencies.

Deadline For Transmittal Of Preapplications: October 18, 1995.

Deadline For Transmittal Of Final Applications: March 18, 1996.

Note: All applicants must submit a preapplication to be eligible to submit a final application.

Deadline For Intergovernmental Review: May 18, 1996.

Applications Available: August 17, 1995.

Available Funds: The Administration's request for the Fund for the Improvement of Postsecondary Education for FY 1996 is $17,543,000. Of this amount, it is anticipated that approximately $5,325,000 will be available for an estimated 75 new awards under the Comprehensive Program. The Congress has not yet completed action on the FY 1996 appropriation. The estimates in this notice assume passage of the Administration's request.

Estimated Range of Awards: $15,000 to $150,000 per year.

Estimated Average Size Of Awards: $71,000.

Estimated Number Of Awards: 75.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR Parts 74, 75, 77, 79, 80, 82, 85, and 86, with the exceptions noted in 34 CFR 630.4a(2); and (b) The regulations for this program in 34 CFR Part 630.

Priorities

Absolute Priority

Under 34 CFR 75.105(c)(3), 34 CFR 630.12 and 34 CFR 630.11(a), the Secretary gives an absolute preference to applications that meet the following priority. The Secretary funds under this competition only applications that meet this absolute priority:

Projects that respond to immediate problems or issues and that seek to improve postsecondary education opportunities.

Invitational Priorities

Under 34 CFR 75.105(c)(1) and 34 CFR 630.12, the Secretary is particularly interested in applications that meet one or more of the following invitational priorities. However, an application that meets one or more of these invitational priorities does not receive competitive

or absolute preference over other applications:

Invitational Priority 1—Applications to support new ways of ensuring equal access to postsecondary education, and to improve rates of retention and program completion, especially for low-income and underrepresented minority students, whose retention and completion rates continue to lag disturbingly behind those of other groups.

Invitational Priority 2—Applications to create programs that prepare students for entering the workforce and that serve the continuing education and retraining needs of workers.

Invitational Priority 3—Applications to improve the campus climate by creating an environment that is safe, welcoming, and conducive to learning for all students.

Invitational Priority 4—Applications to restructure institutions in ways that reassert the primacy of teaching and learning; and to increase learning productivity—that is, to transform programs and teaching to promote more student learning relative to institutional resources expended.

Invitational Priority 5—Applications to promote cooperation between colleges and universities and elementary and secondary schools in order to improve students' preparation for, access to, and success in college. In particular, the Secretary seeks innovative school-college partnerships to improve articulation and develop new ways to improve both pre-service and in-service teacher education at both the elementary and secondary level.

Invitational Priority 6—Applications to support innovative reforms of undergraduate, graduate, and professional curricula that improve not only what students learn, but how they learn.

Invitational Priority 7—Applications to support the development of faculty as professionals by assessing and rewarding effective teaching; helping institutions and faculty find ways to increase their emphasis on teaching and other means of involvement with student learners; promoting new and more effective teaching methods; and improving the preparation—especially the teaching skills—of graduate students who will be future faculty members.

Invitational Priority 8—Recognizing that many innovative postsecondary educational programs have already been locally developed and implemented, the Secretary invites applicants to disseminate these programs to other institutions.

Selection Criteria

In evaluating applications for grants under this program competition, the Secretary uses the following selection criteria chosen from those listed in 34 CFR 630.32:

(a) *Significance for Postsecondary Education*. The Secretary reviews each proposed project for its significance in improving postsecondary education by determining the extent to which it would—

(1) Address an important problem or need;

(2) Represent an improvement upon, or important departure from, existing practice;

(3) Involve learner-centered improvements;

(4) Achieve far-reaching impact through improvements that will be useful in a variety of ways and in a variety of settings; and

(5) Increase the cost-effectiveness of services.

(b) *Feasibility*. The Secretary reviews each proposed project for its feasibility by determining the extent to which—

(1) The proposed project represents an appropriate response to the problem or need addressed;

(2) The applicant is capable of carrying out the proposed project, as evidenced by, for example—

(i) The applicant's understanding of the problem or need;

(ii) The quality of the project design, including objectives, approaches, and evaluation plan;

(iii) The adequacy of resources, including money, personnel, facilities, equipment, and supplies;

(iv) The qualifications of key personnel who would conduct the project; and

(v) The applicant's relevant prior experience;

(3) The applicant and any other participating organizations are committed to the success of the proposed project, as evidenced by, for example—

(i) Contribution of resources by the applicant and by participating organizations;

(ii) Their prior work in the area; and

(iii) The potential for continuation of the proposed project beyond the period of funding (unless the project would be self-terminating); and

(4) The proposed project demonstrates potential for dissemination to or adaptation by other organizations, and shows evidence of interest by potential users.

(c) *Appropriateness of Funding Projects*. The Secretary reviews each application to determine whether support of the proposed project by the Secretary is appropriate in terms of availability of other funding sources for the proposed activities.

Under 630.32, the Secretary determines the methods that will be used in applying the selection criteria.

For preapplications (preliminary applications), the Secretary will give greater weight to the selection criteria under *Significance for Postsecondary Education*. The Secretary will give equal weight to *Feasibility*, and *Appropriateness of Funding Projects*. For final applications (applications), all criteria are equally important. Within each of these criteria, the Secretary gives equal weight to each of the subcriteria. In applying the criteria, the Secretary first analyzes a preapplication or application in terms of each individual criterion and subcriterion. The Secretary then bases the final judgment of an application on an overall assessment of the degree to which the applicant addresses all section criteria.

For Applications or Information Contact: Fund for the Improvement of Postsecondary Education (FIPSE), U.S. Department of Education, 600 Independence Avenue SW., Room 3100, ROB–3, Washington, DC 20202–5175. Telephone: (202) 708–5750 between the hours of 8 a.m. and 5 p.m., Eastern time, Monday through Friday, to order applications or for information. Individuals may also request applications by submitting the name of the competition, their name, and postal mailing address to the e-mail address FIPSE@ED.GOV. Individuals may obtain the application text from Internet address http://www.ed.gov/prog—info/FIPSE/. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

Information about the Department's funding opportunities, including copies of application notices for discretionary grant competitions, can be viewed on the Department's electronic bulletin board (ED Board), telephone (202) 260–9950; or on the Internet Gopher Server at GOPHER.ED.GOV (under Announcements, Bulletins, and Press Releases). However, the official application notice for a discretionary grant competition is the notice published in the **Federal Register**.

Program Authority: 20 U.S.C. 1135–1135a–3.

Dated: August 7, 1995.

David A. Longanecker,

Assistant Secretary for Postsecondary Education.

[FR Doc. 95–20031 Filed 8–11–95; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Financial Assistance Award Intent to Award a Grant to Fusion Lighting, Incorporated for the Office of Energy Efficiency and Renewable Energy

AGENCY: U. S. Department of Energy.

ACTION: Notice of Non-Competitive Financial Assistance Solicitation.

SUMMARY: The Department of Energy announces that pursuant to 10 CFR 600.6(a)(5), it is making a discretionary financial assistance award based on the criterion set forth at 10 CFR 600.7(b)(2)(i)(A) to Fusion Lighting, Incorporated under proposed grant number DE–FG01–95EE23796. Total estimated funding in the amount of $2,620,000 over a period of two years will be provided to Fusion Lighting for this effort. The Department of Energy will provide funding to Fusion Lighting to continue development of both the high and low power versions of the high efficiency Sulfur Lamp (S-Lamp). The following work will be done on each of the following sub-systems common to both the high and low power lamps: (1) development of an electrical power supply for converting power from an electrical power main to radio frequency (RF) or microwave frequency; and (2) output from the power supply (RF or microwave) is matched and coupled to the light emitting bulb.

The Department of Energy has determined in accordance with 10 CFR 600.7(b)(2)(i)(A) that the ''the activity is necessary to the satisfactory completion of, or is a continuation or renewal of, an activity presently being funded by the Department of Energy or another Federal agency, and for which competition for support would have a significant adverse effect on continuity or completion of the activity.'' The continuity of the effort is critical at this time in order to maintain research momentum and research staff. It is also highly important to follow up as soon as possible on consequences and applications related to the initial discovery and development of the lamp.

Fusion Lighting has been involved in the development of both low and high power versions for the S-Lamp. They have identified personnel and resources capable of performing the activities, and they have extensive experience related to this research.

This award will serve the public by supporting efforts to develop an illumination source which is energy efficient and environmentally friendly. This technology could result in considerable savings for consumers in electric energy expenditures, as well as reductions in environmental pollutants produced by electrical generating plants.

The period of performance is two years from the date of award.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Energy, Office of Placement and Administration, Attn: Berta Schreiber, HR–561.21, 1000 Independence Avenue SW., Washington, DC 20036.

Bertha Schreiber,

Headquarters Operations, Division B, Office of the Associate Deputy Assistant, Secretary for Headquarters Procurement.Operations

[FR Doc. 95–20033 Filed 8–11–95; 8:45 am]

BILLING CODE 6450–01–P

Environmental Management Site Specific Advisory Board, Pantex Plant

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770) notice is hereby given of the following Advisory Committee meeting: Environmental Management Site Specific Advisory Board (EM SSAB), Pantex Plant.

DATE AND TIME: Tuesday, August 22, 1995: 1:30 pm–5:30 pm.

ADDRESS: Carson County Square House Museum, 5th and Elsie, Panhandle, Texas.

FOR FURTHER INFORMATION CONTACT: Tom Williams, Program Manager, Department of Energy, Amarillo Area Office, P.O. Box 30030, Amarillo, TX 79120 (806)477–3121.

SUPPLEMENTARY INFORMATION: Purpose of the Committee: The Environmental Management Site Specific Advisory Board, Pantex Plant provides input to the Department of Energy on Environmental Management strategic decisions that impact future use, risk management, economic development, and budget prioritization activities.

Tentative Agenda

1:30 pm Welcome— Agenda Review— Introductions
1:40 pm Co-Chairs' Comments
2:00 pm Task Force Reports— Discussion
Public Participation/Public Information
Environmental Restoration
Site-wide Environmental Impact Statements
Future of the Nuclear Complex
Waste Management
3:15 pm Break
3:30 pm Presentation—Draft Site Treatment Plan—Discussion Panel
4:15 pm Updates
Occurrence Reports—DOE
4:30 pm Subcommittee Reports
- Budget and Finance
- Policy and Personnel
- Program and Training
- Community Outreach
- Nominations

5:30 pm Adjourn.

Public comment will be taken periodically throughout the meeting.

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Written comments will be accepted at the address above for 15 days after the date of the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Tom Williams' office at the address or telephone number listed above. Requests should be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Official is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments. This notice is being published less than 15 days before the date of the meeting, due to programmatic issues that had to be resolved prior to publication.

Minutes: The minutes of this meeting will be available for public review and copying at the Pantex Public Reading Rooms located at the Amarillo College Lynn Library and Learning Center, 2201 South Washington, Amarillo, TX phone (806)371–5400. Hours of operation are from 7:45 am to 10:00 pm, Monday through Thursday; 7:45 am to 5:00 pm on Friday; 8:30 am to 12:00 noon on Saturday; and 2:00 pm to 6:00 pm on Sunday, except for Federal holidays. Additionally, there is a Public Reading Room located at the Carson County Public Library, 401 Main Street, Panhandle, TX phone (806)537–3742. Hours of operation are from 9:00 am to 7:00 pm on Monday; 9:00 am to 5:00 pm, Tuesday through Friday; and closed Saturday and Sunday as well as Federal Holidays. Minutes will also be available

by writing or calling Tom Williams at the address or telephone number listed above.

Issued at Washington, DC on August 9, 1995.

Rachel M. Samuel,

Acting Deputy Advisory Committee Management Officer.

[FR Doc. 95–20034 Filed 8–11–95; 8:45 am]

BILLING CODE 6450–01–P

Federal Energy Regulatory Commission

[Docket No. RP95–182–000]

ANR Pipeline Co.; Notice of Technical Conference

August 8, 1995.

In the Commission's order issued March 31, 1995, in the above-captioned proceeding, the Commission held that the filing raised issues for which a technical conference was to be convened. A technical conference to address the issues was held Thursday, July 27, 1995. Comments are scheduled to be filed by August 15, 1995, with reply comments to be filed by August 30, 1995.

ANR Pipeline Company and certain intervenors have asked the Commission to schedule a further session of the technical conference in an effort to resolve the disputed issues. Accordingly, the requested conference has been scheduled for Tuesday, August 22, 1995, at 10:00 a.m. in a room to be designated at the offices of the Federal Energy Regulatory Commission, 810 First Street, NE., Washington, DC 20426. The due dates for comments and reply comments remain unchanged.

All interested persons and Staff are permitted to attend.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 95–19966 Filed 8–11–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. MG95–7–000]

Cove Point LNG Limited Partnership; Notice of Filing

August 8, 1995.

Take notice that on July 31, 1995, Cove Point LNG Limited Partnership (Cove Point) filed its standards of conduct in compliance with Section 161.3(i), 18 CFR 161.3 (i), Order Nos. 497 *et seq.* [1] and Order Nos. 566 *et seq.*[2]

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C., 20426, in accordance with Rules 211 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 23, 1995). Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.

Acting Secretary.

[FR Doc. 95–19963 Filed 8–11–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. EL95–67–000]

Florida Power Corporation v. Tampa Electric Company; Notice of Filing

August 8, 1995.

Take notice that on July 31, 1995, Florida Power Corporation (FPC) tendered for filing a complaint against Tampa Electric Company (TECO). FPC requests that the Commission investigate whether TECO has collected or will collect excessive charges through its fuel adjustment clause by discounting the fuel component of energy sold to other utilities to less than incremental cost and requiring other customers to subsidize the discounts through the fuel clause.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before September 7, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. Answers to the complaint shall be due on or before September 7, 1995.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 95–19962 Filed 8–11–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–192–008]

Texas Eastern Transmission Corp.; Notice of Proposed Changes in FERC Gas Tariff

August 8, 1995.

Take notice that on August 4, 1995, pursuant to and in compliance with the Commission's June 15, 1995, Letter Order in Docket Nos. RP93–192–000 and RP93–192–001, Texas Eastern Transmission Corporation (Texas Eastern) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, the following tariff sheet:

Seventh Revised Sheet No. 42B

Texas Eastern states that in compliance with Article III.B. of the April 25, 1995 Amended Joint Offer of Settlement and the Commission's June 15, 1995 Letter Order in Docket Nos. RP93–192–000 and RP93–192–001, the tariff sheet submitted reflects a reduction in the maximum rate of $0.1139 to $0.10 for Rate Schedules VKFT and VKIT.

Texas Eastern requests that the above referenced tariff sheets become effective on August 1, 1995. Copies of the filing were served on: (1) Firm customers of Texas Eastern, (2) interested state commission, (3) all parties on the

[1] Order No. 497, 53 FR 22139 (June 14, 1988), III FERC Stats. & Regs. ¶ 30,820 (1988); Order No. 497–A, *order on rehearing,* 54 FR 52781 (December 22, 1989), III FERC Stats. & Regs. 30,868 (1989); Order No. 497–B, *order extending sunset date,* 55 FR 53291 (December 28, 1990), III FERC Stats. & Regs. ¶ 30,908 (1990); Order No. 497–C, *order extending sunset date,* 57 FR 9 (January 2, 1992), III FERC Stats. & Regs. ¶ 30,934 (1991), rehearing denied, 57 FR 5815 (February 18, 1992), 58 FERC ¶ 61,139 (1992); Tenneco Gas v. FERC (affirmed in part and remanded in part), 969 F.2d 1187 (D.C. Cir. 1992); Order No. 497–D, *order on rehearing and extending sunset date,* III FERC Stats. & Regs. ¶ 30,958 (December 4, 1992), 57 FR 58978 (December 14, 1992); Order No. 497–E, *order on rehearing and extending sunset date,* 59 FR 243 (January 4, 1994), 65 FERC ¶ 61,381 (December 23, 1993); Order No. 497–F, *order denying rehearing and granting clarification,* 59 FR 15336 (April 1, 1994), 66 FERC ¶ 61,347 (March 24, 1994); and Order No. 497–G, *order extending sunset date,* 59 FR 32884 (June 27, 1994), III FERC Stats. & Regs. ¶ 30,996 (June 17, 1994).

[2] Standards of Conduct and Reporting Requirements for Transportation and Affiliate Transactions, Order No. 566, 59 FR 32885 (June 27, 1994), III FERC Stats. & Regs. ¶ 30,997 (June 17, 1994); Order No 566–A, *order on rehearing,* 59 FR 52896 (October 20, 1994), 69 FERC ¶ 61,044 (October 14, 1994); Order No. 566–B, *order on rehearing,* 59 FR 65707, (December 21, 1994); 69 FERC ¶ 61,334 (December 14, 1994); *appeal docketed sub nom. Conoco, Inc. v. FERC,* D.C. Cir. No. 94–1745 (December 13, 1994).

Commission's service list in Docket Nos. RP93–192–000 and RP93–192–001 and (4) all current shippers utilizing the Viosca Knoll Lateral.

Any person desiring to protect said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with § 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before August 15, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 95–19964 Filed 8–11–95; 8:45 am]

BILLING CODE 6717–01–M

Wyoming Interstate Company, Ltd.; Notice of Filing of Refund Report

August 8, 1995.

Take notice that on August 2, 1995, Wyoming Interstate Company, Ltd. (WIC) filed a refund report in Docket No. RP94–267–006. WIC states that the filing and refunds were made to comply with the Federal Energy Regulatory Commission's order of March 3, 1995. WIC states that the refund amounts were paid by WIC on July 3, 1995.

WIC further states that the refund report summarizes transportation refund amounts for the period December 1, 1994 through May 31, 1995.

WIC states that copies of this filing were served on each person designated on the Commission's official service in this proceeding, and are otherwise available for public inspection at WIC's offices in Colorado Springs, Colorado.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington D.C. 20426, in accordance with § 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before August 15, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 95–19965 Filed 8–11–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP94–763–000]

Northern Natural Gas Co.; Notice of Availability of the Environmental Assessment for the Proposed Peoples/L.S. Power-Cottage Grove Project

August 8, 1995.

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.

The EA was prepared to satisfy the requirements of the National Environmental Policy Act. The staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

The EA assesses the potential environmental effects of the construction and operation of Northern's proposed Peoples/L.S. Power-Cottage Grove Project, which includes the following facilities:

- about 1.42 miles of 30-inch-diameter pipeline to loop its existing 24-inch-diameter pipeline (MNM 86501) in Washington County, Minnesota;
- a new L.S. Power-Cottage Grove Town Border Station in Washington County, Minnesota; and
- a 1,250-horsepower electric-motor driven compressor at Northern's existing Farmington Compressor Station in Dakota County, Minnesota.

Northern indicates the proposed facilities would deliver an additional firm transportation capacity of 29,120 thousand cubic feet per day of natural gas to Peoples Natural Gas Company and L.S. Power-Cottage Grove Limited Partnership (L.S. Power-Cottage Grove) for the L.S. Power-Cottage Grove cogneration Plant.

The EA has been placed in the public files of the FERC and is available for public inspection at:

Federal Energy Regulatory Commission, Public Reference and Files Maintenance Branch, 941 North Capitol Street NE., Room 3104, Washington, DC 20426 (202) 208–1371.

Copies of the EA have been mailed to Federal, state and local agencies, public interest groups, interested individuals, newspapers, and parties to this proceeding.

A limited number of copies of the EA are available from:

Mr. Hugh Thomas, Environmental Project Manager, Environmental Review and Compliance Branch I, Office of Pipeline Regulation, Room 7312, 825 North Capitol Street NE., Washington, DC 20426, (202) 208–0980.

Any person wishing to comment on the EA may do so. Written comments must reference Docket No. CP94–763–000. Comments should be addressed to:

Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426.

Comments should be filed as soon as possible, but must be received no later than September 7, 1995, to ensure consideration prior to a Commission decision on this proposal. A copy of any comments should also be sent to Mr. Hugh Thomas, Environmental Project Manager, at the above address.

Comments will be considered by the Commission but will not serve to make the commentor a party to the proceeding. Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedure (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 reviewed as good cause for late intervention. You do not need intervenor status to have your comments considered.

Additional information about this project is available from Mr. Hugh Thomas, Environmental Review and Compliance Branch I, Office of Pipeline Regulation, at (202) 208–0980.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 95–19961 Filed 8–11–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. EG95–71–000, et al.]

Empresa Valle Hermoso, S.A., et al.; Electric Rate and Corporate Regulation Filings

August 7, 1995.

Take notice that the following filings have been made with the Commission:

1. Empresa Valle Hermoso, S.A.

[Docket No. EG95–71–000]

On July 31, 1995, Empresa Valle Hermoso, S.A. (''Hermoso''), with its address c/o OPDB, Ltd., 40 Lane Road, Fairfield, NJ 07007–2615, filed with the Federal Energy Regulatory Commission (''FERC'' or the ''Commission'') an application for determination of exempt wholesale generator status pursuant to part 365 of the Commission's regulations.

Hermoso, S.A. is a Cayman Island limited liability company that will be engaged indirectly through one or more affiliates as defined in Section 2(a)(11)(b) of the Public Utility Holding Company Act of 1935, as amended (''PUHCA''), or directly, and exclusively in the business of owning and or operating, or both owning and operating, all or part of one or more eligible facilities located in Bolivia. The eligible facilities consist of approximately 87.2 MW of existing gas fired generation plants and related interconnection facilities and an approximately 126 MW gas fired electric generation plant and related interconnection facilities that is currently under construction. The output of the eligible facilities is, or will be, sold at wholesale except that to the extent permitted by Bolivian law retail power sales may be made to consumers located in Bolivia.

Comment date: August 25, 1995, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. The Southwire Company

[Docket No. ER94–446–000]

Take notice that The Southwire Company, on July 25, 1995, tendered for filing amendment to its Initial Rate Filing of approval to sell surplus energy at market-based rates. The Southwire Company has submitted a proposed FERC Rate Schedule No. 1 which establishes certain maximum rates for sales of electric energy to Oglethorpe Power Corporation. Consistent with its Initial Rate Filing, Southwire has requested waiver of the 60-day notice period and a retroactive effective date.

Copies of this filing were served upon Oglethorpe Power Corporation, Carroll Electric Membership Corporation, and Georgia Public Service Commission.

Comment date: August 21, 1995, in accordance with Standard Paragraph E at the end of this notice.

3. Wisconsin Public Service Corporation

[Docket No. ER95–576–001]

Take notice that Wisconsin Public Service Corporation (WPSC) of Green Bay, Wisconsin on July 21, 1995, tendered for filing a revision to its June 30, 1995 SO_2 emission allowance filing to comply with the Commission's June 2, 1995 order accepting WPSC's February 8, 1995 emission allowance filing. WPSC asks that its emission allowance rate, as amended by its current filing, become effective on July 1, 1995.

WPSC states that the filing has been served on the affected parties and posted as required by the Commission's regulations.

Comment date: August 21, 1995, in accordance with Standard Paragraph E at the end of this notice.

4. Southern Indiana Gas and Electric

[Docket No. ER95–599–000 Company]

Take notice that Southern Indiana Gas and Electric Company tendered for filing an amendment in the above-referenced docket.

Comment date: August 21, 1995, in accordance with Standard Paragraph E at the end of this notice.

5. Jersey Central Power & Light Company, Metropolitan Edison Company, Pennsylvania Electric Company

[Docket No. ER95–791–000]

Take notice that on July 31, 1995, GPU Service Corporation (GPU), on behalf of Jersey Central Power & Light Company, Metropolitan Edison Company and Pennsylvania Electric Company, submitted for filing certain amendments to, and testimony in support of, the Firm Power Transmission Service and Energy Transmission Service Tariffs originally filed with the Commission on March 22, 1995. GPU requests an effective date of September 29, 1995.

Comment date: August 21, 1995, in accordance with Standard Paragraph E at the end of this notice.

6. Portland General Electric Company

[Docket No. ER95–1128–000]

Take notice that on July 31, 1995, Portland General Electric Company (PGE) tendered for filing an amendment to its filing in this docket.

Comment date: August 17, 1995, in accordance with Standard Paragraph E at the end of this notice.

7. Northern States Power Company (Minnesota), Northern States Power Company (Wisconsin)

[Docket No. ER95–1389–000]

Take notice that on July 18, 1995, Northern States Power Company-Minnesota (NSP-M) and Northern States Power Company-Wisconsin (NSP-W) jointly tendered and request the Commission to accept a Transmission Service Agreement which provides for 30 MW of Reserved Transmission Service to Wisconsin Power and Light Company. The source party is Basin Electric Power Cooperative and the recipient party is Wisconsin Power and Light Company.

NSP requests that the Commission accept for filing the Transmission Service Agreement effective as of June 1, 1995. NSP requests a waiver of the Commission's notice requirements pursuant to Part 35 so the Agreement may be accepted for filing effective on the date requested.

Comment date: August 21, 1995, in accordance with Standard Paragraph E at the end of this notice.

8. Southern California Edison Company

[Docket No. ER95–1404–000]

Take notice that on July 20, 1995, Southern California Edison Company tendered for filing a Notice of Cancellation of FERC Rate Schedule No. 263 and all supplements thereto in the above-referenced docket.

Comment date: August 21, 1995, in accordance with Standard Paragraph E at the end of this notice.

9. IES Utilities Inc.

[Docket No. ER95–1444–000]

Take notice that on July 28, 1995, IES Utilities Inc. tendered for filing its proposed Open Access Transmission Tariffs and supporting documents.

Comment date: August 21, 1995, in accordance with Standard Paragraph E at the end of this notice.

10. San Diego Gas & Electric Company

[Docket No. ER95–1447–000]

Take notice that on July 31, 1995, San Diego Gas & Electric Company (SDG&E) tendered for filing an Interchange Agreement (Agreement) between SDG&E and Heartland Energy Services, Inc. (Heartland).

SDG&E requests that the Commission allow the Agreement to become effective on the 2nd day of October, 1995 or at the earliest possible date.

Copies of this filing were served upon the Public Utilities Commission of the State of California and Heartland.

Comment date: August 21, 1995, in accordance with Standard Paragraph E at the end of this notice.

11. Pacific Gas and Electric Company

[Docket No. ER95–1448–000]

Take notice that on July 31, 1995, Pacific Gas and Electric Company (PG&E) tendered for filing two requests from customers for changes in transmission service and corresponding revised exhibits to interconnection agreements. The materials filed are: (1) A letter from the Central California Power Agency No. 1 (CCPA), dated June 8, 1995, requesting reduction in the amount of transmission service under the ''Superseding Agreement for Transmission Service for the Coldwater Creek Geothermal Power Plant Between Pacific Gas and Electric Company and CCPA No. 1 Member Utilities'', PG&E Rate Schedule FERC No. 174; (2) a letter from the Sacramento Municipal Utility District (SMUD), dated June 8, 1995, requesting reduction in the amount of transmission service under the ''Superseding Agreement for Coldwater Creek Geothermal Power Plant Backbone Transmission Service Between Pacific Gas and Electric Company and Sacramento Municipal Utility District'', PG&E Rate Schedule FERC No. 175; (3) a revised Appendix E to Rate Schedule FERC No. 136, the PG&E-SMUD Interconnection Agreement, reflecting the requested reduction, and (4) a revised Exhibit A–4 to Rate Schedule FERC No. 85, the PG&E-City of Santa Clara Interconnection Agreement, reflecting the requested reduction.

The proposed reductions in transmission service are intended to become effective on October 1, 1995.

Copies of this filing have been served upon CCPA, the Modesto Irrigation District, Santa Clara, SMUD and the California Public Utilities Commission.

Comment date: August 21, 1995, in accordance with Standard Paragraph E at the end of this notice.

12. Duke Power Company

[Docket No. ER95–1449–000]

Take notice that on July 31, 1995, Duke Power Company (Duke) filed a supplement to its Electric Power Contract with Kings Mountain, North Carolina. This contract is on file with the Commission and has been designated Duke Power Company Rate Schedule FERC No. 10. The supplement provides for a decrease in contract demand at Delivery Point No. 1 to 1000 kW at the request of the customer.

Comment date: August 21, 1995, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 95–19967 Filed 8–11–95; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5274–6]

Proposed Prospective Purchaser Agreement Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as Amended by the Superfund Amendments and Reauthorization Act

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended by the superfund Amendments and Reauthorization Act of 1986 (''CERCLA''), 42 U.S.C. 9600 *et seq.*, notice is hereby given that a proposed prospective purchaser agreement associated with the San Gabriel Valley Superfund Sites, Areas 1–4 in Los Angeles County California was executed by the United States Environmental Protection Agency (''EPA'') on May 26, 1995, and has been approved by the United States Department of Justice. The proposed prospective purchaser agreement would resolve certain potential claims of the United States under sections 106 and 107 of CERCLA, 42 U.S.C. 9606 and 9607, and Section 7003 of the Solid Waste Disposal Action, as amended, 42 U.S.C. 6973, against Sargent Fletcher Inc. (the ''Purchaser''). The proposed settlement would require the purchaser to pay EPA a one-time payment of $500,000; to implement state lead response actions at the purchased property; and to implement a multi-media environmental program at the facility according to an EPA work plan,.

For thirty (30) calendar days following the date of publication of this notice, EPA will receive written comments relating to the proposed settlement. If requested on or before September 5, 1995, EPA will provide an opportunity for a public meeting in the effected area. EPA's response to any comments received will be available for public inspection at the U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

DATES: Comments must be submitted on or before September 13, 1995.

AVAILABILITY: The proposed prospective purchaser agreement and additional background information relating to the settlement are available for public inspection at the U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105. A copy of the proposed settlement may be obtained from Mark Klaiman, Assistant Regional Counsel (RC–3–1), Office of Regional Counsel, U.S. EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105. Comments should reference ''Sargent Fletcher Inc., San Gabriel Valley Superfund Sites Areas 1–4'' and ''Docket No. 95–08'' and should be addressed to Mark Klaiman at the above address.

FOR FURTHER INFORMATION CONTACT: Mark Klaiman, Assistant Regional Counsel (RC–3–1), Office of Regional Counsel, U.S. EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105, (415) 744–1374.

Dated: July 20, 1995.

Jeff Zelikson,

Director, Hazardous Waste Management Division, U.S. EPA, Region IX.

[FR Doc. 95–19997 Filed 8–11–95; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1061–DR]

Oregon; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Oregon (FEMA–1061–DR), dated August 3, 1995, and related determinations.

EFFECTIVE DATE: August 3, 1995.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated August 3, 1995, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), as follows:

I have determined that the damage in certain areas of the State of Oregon, resulting from flash flooding on July 8–9, 1995, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (''the Stafford Act''). I, therefore, declare that such a major disaster exists in the State of Oregon.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation Assistance in the designated area. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Robert C. Freitag of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following area of the State of Oregon to have been affected adversely by this declared major disaster: The County of Wasco for Public Assistance and Hazard Mitigation Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

James L. Witt,

Director.

[FR Doc. 95–20006 Filed 8–11–95; 8:45 am]

BILLING CODE 6718–02–M

[FEMA–3116–EM]

Florida; Emergency Declaration and Related Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Florida (FEMA–3116–EM), dated August 3, 1995, and related determinations.

EFFECTIVE DATE: August 3, 1995.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated August 3, 1995, the President declared an emergency under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), as follows:

I have determined that the damage in certain areas of the State of Florida, resulting from Hurricane Erin on August 2–3, 1995, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (''the Stafford Act''). I, therefore, declare that such an emergency exists in the State of Florida.

You are authorized to coordinate all emergency efforts which have the purpose of alleviating the hardship and suffering caused by the emergency on the local population, and to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives, protect property and public health and safety, and lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to identify, mobilize, and provide at your discretion, equipment and resources necessary to alleviate the impacts of the emergency for the seven day period of August 2, 1995 through August 8, 1995.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal emergency assistance and administrative expenses. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Glenn C. Woodard of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Florida to have been affected adversely by this declared emergency:

The counties of Escambia, Santa Rosa, Okaloosa, Walton, Bay, Gulf, Calhoun, Washington, Holmes, Jackson, Franklin, Wakulla, and Brevard for assistance as follows: FEMA intends to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives, protect property and public health and safety, and lessen or avert the threat of a catastrophe in the designated areas. Specifically, FEMA intends to identify, mobilize, and provide at its discretion, equipment and resources necessary to alleviate the impacts of the emergency for the seven day period of August 2, 1995 through August 8, 1995.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

James L. Witt,

Director.

[FR Doc. 95–20007 Filed 8–11–95; 8:45 am]

BILLING CODE 6718–01–M

[FEMA–1055–DR]

Kentucky; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Kentucky (FEMA–1055–DR), dated June 13, 1995, and related determinations.

EFFECTIVE DATE: August 3, 1995.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of Kentucky dated June 13, 1995, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of June 13, 1995:

Cumberland County for Public Assistance and Hazard Mitigation Assistance.

The Counties of Christian, Laurel, and Pike for Hazard Mitigation Assistance (already designated for Individual Assistance.)

The Counties of Fulton, Jackson, Perry, and Rockcastle for Hazard Mitigation

Assistance (already designated for Public Assistance.)

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

James L. Witt,

Director.

[FR Doc. 95–20005 Filed 8–11–95; 8:45 am]

BILLING CODE 6718–02–M

FEDERAL RESERVE SYSTEM

Allen C. Barbieri, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 28, 1995.

A. Federal Reserve Bank of San Francisco (Kenneth R. Binning, Director, Bank Holding Company) 101 Market Street, San Francisco, California 94105:

1. Allen C. Barbieri, Irvine, California; to acquire an additional 3.64 percent, for a total of 5.93 percent; Martin T. Hart, Denver Colorado, to acquire an additional 15.26 percent, for a total of 19.42; Doug L. Heller, Irvine, California, to acquire an additional .97 percent for a total of 1.28 percent; G. Mitchell Morris, Salt Lake City, Utah, to acquire an additional 10.69 percent, for a total of 11.52 percent, Jon A. Salquist, Portland, Oregon, to acquire an additional 10.69 percent, for a total of 11.52 percent, James K. Schuler, Honolulu, Hawaii, to acquire an additional 15.26 percent, for a total of 18.14 percent (acting in concert), of the voting shares of PNB Financial Group, Newport Beach, California, and thereby indirectly acquire Pacific National Bank, Newport Beach, California.

2. John C. Bell; John C. Bell Family Trust; and K & G Trust, all of Burbank, California; to acquire an additional 4.67 percent, for a total of 13.83 percent, of the voting shares of Western Security Bancorp, Burbank, California, and thereby indirectly acquire Western Security Bank National Association, Burbank, California.

Board of Governors of the Federal Reserve System, August 8, 1995.

William W. Wiles,

Secretary of the Board.

[FR Doc. 95–19983 Filed 8–11–95; 8:45 am]

BILLING CODE 6210–01–F

Merchants Bancorp, Inc., et al. Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than September 7, 1995.

A. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Merchants Bancorp, Inc., Aurora, Illinois; to acquire 100 percent of the voting shares of Valley Banc Services Corp., St. Charles, Illinois, and thereby indirectly acquire Anchor Bank, Grayslake, Illinois; Fox Valley Bank, St. Charles, Illinois; Hinckley State Bank, Hinckley, Illinois; and State Bank of Osco, Osco, Illinois.

2. WFC, Inc., Waukon, Iowa; to acquire 100 percent of the voting shares of Viking State Bank & Trust, Decorah, Iowa (in organization).

B. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Western Dakota Holding Company, Timber Lake, South Dakota; to become a bank holding company by acquiring 50.02 percent of the voting shares of Dewey County Bank, Timber Lake, Minneosta.

C. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. BFM Bancshares, Inc., Kingman, Kansas; to become a bank holding company by acquiring 81.025 percent of the voting shares of State Bank of Kingman, Kingman, Kansas.

2. Unison Bancorp, Inc., Lenexa, Kansas; to become a bank holding company by acquiring 100 percent of the voting shares of Western National Bank, Lenexa, Kansas (in formation).

Board of Governors of the Federal Reserve System, August 8, 1995.

William W. Wiles,

Secretary of the Board.

[FR Doc. 95–19984 Filed 8–11–95; 8:45 am]

BILLING CODE 6210–01–F

401 K Plan and ESOP of United States Trust Company of New York and Affiliated Companies; Formation of, Acquisition by, or Merger of Bank Holding Companies; and Acquisition of Nonbanking Company

The company listed in this notice has applied under § 225.14 of the Board's Regulation Y (12 CFR 225.14) for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) to become a bank holding company or to acquire voting securities of a bank or bank holding company. The listed company has also applied under § 225.23(a)(2) of Regulation Y (12 CFR 225.23(a)(2)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies, or to engage in such an activity. Unless otherwise noted, these activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the

question whether consummation of the proposal can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices.'' Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 7, 1995.

A. Federal Reserve Bank of New York (William L. Rutledge, Senior Vice President) 33 Liberty Street, New York, New York 10045:

1. 401 K Plan and ESOP of United States Trust Company of New York New York, New York; to become a bank holding company by acquiring between 25 and 35 percent of the voting shares of New USTC Holdings Corporation, New York, New York (''New Holdings''), and thereby indirectly acquire New U.S. Trust Company of New York, New York, New York; U.S. Trust Company of Texas, N.A., Dallas, Texas; and U.S. Trust Company of California, N.A., Los Angeles, California.

In connection with this application, Applicant also has applied to acquire U.S. Trust Company of Florida Savings Bank, Palm Beach, Florida, and thereby engage in trust company, investment and financial advisory, community development, and savings association operations activities, pursuant to §§ 225.25(b)(3), (4), (6), and (9), of the Board's Regulation Y; [2] through CTMC Holding Company and its wholly-owned subsidiaries, U.S. Trust Company of the Pacific Northwest, and CTC Consulting, all of Portland, Oregon, in trust company, and investment and financial advisory activities pursuant to §§ 225.25(b)(3) and (4) of the Board's Regulation Y, respectively, [3] through Campbell, Cowperthwait & Co., Inc., New York, New York, in investment or financial advice pursuant to § 225.25(b)(4) of the Board's Regulation Y, [4] through U.S. Trust Company of New Jersey and its wholly-owned subsidiary, U.S.T. Securities Corp., both of Princeton, New Jersey, in trust company, investment and financial advisory, securities brokerage, and riskless principal activities pursuant to §§ 225.25(b)(3), (4), (15) of the Board's Regulation Y and previous Board order (U.S. Trust Corporation, 78 *Federal Reserve Bulletin* 336, (1992)), respectively, and [5] through U.S. Trust Company of Connecticut, Stamford, Connecticut, in trust company and investment and financial advisory activities pursuant to §§ 225.25(b)(3) and (4) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, August 8, 1995.

William W. Wiles,

Secretary of the Board.

[FR Doc. 95–19985 Filed 8–11–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Notice of Evaluation of Medical Technology

The Agency for Health Care Policy and Research (AHCPR), through the Center or Health Care Technology (CHCT) (formerly OHTA), announces that it is conducting an evaluation of the safety, effectiveness, and clinical utility of positron emission tomography (PET), using fluorine 18 labelled 2-deoxy-2-fluoro-D-glucose (FDG), as a diagnostic and management tool for use in patients with focal or partial epilepsy.

This evaluation will be concerned with the use of FDG–PET in the localization of seizure focus for possible surgical excision and seeks to answer the following questions: (1) Does FDG–PET provide information of value to a clinician that is not otherwise available? (2) What is the extent of any incremental benefit obtained from the use of FDG–PET when the information obtained is comparable to that available from other diagnostic modalities? (3) How does the sensitivity and specificity of FDG–PET compare with other diagnostic modalities currently in use? (4) Where does FDG–PET fit in the overall scheme of diagnostic testing? Should it be used in lieu of, or in addition to other diagnostic modalities? (5) What patient selection criteria should be applied?

AHCPR is interested in receiving information based on review and assessment of past, current, and planned research related to this technology, as well as a bibliography of published, controlled clinical trials and other well-designed clinical studies. Also requested is information related to the characteristics of the patient population most likely to benefit from the use of FDG–PET as well as information on the clinical acceptability, effectiveness, and the extent of use of this technology. Information relevant to this review should be submitted in writing to CHCT at the address below.

To enable the interested scientific community to evaluate the information included in this review, AHCPR will discuss in the review only those data and analyses for which a source(s) can be cited. Respondents are therefore encouraged to include with their submission a written consent permitting AHCPR to cite the source of the data and comments provided. Otherwise, in accordance with the confidentiality statute governing information collected by AHCPR, 42 U.S.C. 299a–1(c), no information received will be published or disclosed which could identify an individual or entity described in the information or could identify an entity or individual supplying the information.

Dependent upon the quality and quantity of the scientific data, CHCT will prepare an assessment, review, or other evaluation of the technology under consideration. (The AHCPR Technology Assessment process was described in the December 3, 1993 **Federal Register** (58 FR 63988)).

Written material should be submitted to: Thomas V. Holohan, M.D., Acting Director, Center for Health Care Technology, Agency for Health Care Policy and Research, 6000 Executive Boulevard, Suite 309, Rockville, MD 20852, Phone: (301) 594–4023, Fax: (301) 594–4030.

Dated: August 8, 1995.

Clifton R. Gaus,

Administrator.

[FR Doc. 95–19991 Filed 8–11–95; 8:45 am]

BILLING CODE 4160–90–M

Food and Drug Administration

[Docket No. 95N–0228]

Pharmaceutical Marketing and Information Exchange in Managed Care Environments; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing regarding pharmaceutical marketing and information exchange in managed care environments. FDA is seeking information and views concerning the potential impact of

changing organizational structures and information dissemination channels in the managed care setting on the agency's responsibilities to regulate drug marketing and promotion. The agency is particularly interested in exploring the issues surrounding new modes and techniques of drug information dissemination (e.g., the communication of cost-effectiveness claims) and the formation of alliances between manufacturers and prescription benefit management companies (PBM's).

DATES: The public hearing will be held on October 19, 1995, from 1:30 p.m. to 5:30 p.m., and October 20, 1995, from 8:30 a.m. to 5:30 p.m. Submit written notices of participation *by September 15, 1995*. Written *comments* will be accepted *until December 29, 1995*.

ADDRESSES: The public hearing will be held at the Quality Hotel–Silver Spring, 8727 Colesville Rd., Silver Spring, MD 20910. Submit written notices of participation and comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with docket number 95N–0228. Transcripts of the hearing will be available for review at the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: Lee L. Zwanziger, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Food, Drug, and Cosmetic Act, FDA has responsibility for regulating the labeling and advertising of prescription drugs. Specifically, the agency reviews promotional materials disseminated by, or on behalf of, prescription drug manufacturers for consistency with approved drug product labeling, and to ensure that these materials are accurate, contain proper disclosures, and ''fair balance'' in terms of benefit and risk information. Underlying this responsibility is a public health concern that health care professionals and patients base their decisions about drug products on sound scientific data and information.

Traditionally, health care providers, patients, pharmacists, and pharmaceutical manufacturers have been separate entities with independent functions. However, the relationships among health care providers, pharmaceutical manufacturers, and health benefits managers are changing. The rapid growth of managed health care, with its emphasis on managing the quality of care while controlling costs, has dramatically changed pharmaceutical purchasing. Consequently, pharmaceutical marketing has also changed to emphasize value in addition to safety and effectiveness. Direct comparative effectiveness, safety, and cost-effectiveness information has become more prevalent as a basis for promotional claims.

Furthermore, the audience for prescription drug promotion has also changed. The importance of institutional decisionmakers as recipients of marketing communications has increased. Over the past several months, several pharmaceutical manufacturers have formed business relationships with or have purchased companies that manage pharmacy benefits (i.e., PBM's). FDA has received reports that these entities are disseminating information to formulary decisionmakers, prescribers, and users about the allied manufacturer's drug products. Moreover, pharmacist employees of certain PBM's have telephoned prescribers to request that they switch their patients to the drug products of their employer's allied manufacturer.

Several pharmaceutical manufacturers have approached FDA about its policies regarding the dissemination of pharmacoeconomic information, especially comparative cost-effectiveness analyses of pharmaceutical products. In response to these inquiries, FDA has stated that ''effectiveness'' elements of cost-effectiveness claims must be based on adequate and well-controlled studies and cost elements should be substantiated by adequate disclosure of both prices and methods used to derive the cost estimates. In addition, the Division of Drug Marketing, Advertising and Communications (DDMAC) has circulated a draft set of principles for use in evaluating pharmacoeconomic claims.

Some have asserted that the dissemination of information by the pharmaceutical industry to managed care providers (e.g., formulary managers) need not meet traditional standards of substantiation because the audience is highly educated and able to regulate the process by creating a demand for supporting studies that display scientific rigor.

In addition, they maintain that these audiences may impose corrective measures (e.g., formulary exclusions), which would drive up the quality of pharmacoeconomic analyses. However, the proponents also suggest that the increased costs and time needed to conduct multiple studies with sufficient methodological rigor are prohibitive and that their customers are demanding information that, in some instances, may only be provided by the use of less expensive techniques such as administrative data base analysis and modeling.

The agency recognizes that these issues affect both the manufacturers' desire to provide drug information and the managed health care industry's need for this information. Accordingly, FDA seeks to investigate the implications of these issues on its regulatory responsibilities.

II. Scope of the Hearing

In light of the many complex scientific and public health issues raised by the evolution of the health care environment, FDA is soliciting broad public participation and comment on the potential implications of these changes on pharmaceutical regulation. The agency encourages individuals with information relevant to these changes to respond to this notice. FDA is interested in a broad range of issues including:

(1) *Changing business relationships*. What are the implications of the changing health care market on pharmaceutical communications and promotion? Should FDA regulations be modified? If yes, how should the agency's regulations be modified? How would these modifications affect FDA's public health responsibilities?

(2) *Changing marketing claims*. How are pharmacoeconomic claims different from traditional comparative claims between therapeutically similar drugs or therapies? What should be FDA's goal in monitoring cost-effectiveness claims? What level of support is necessary to substantiate cost-effectiveness claims?

(3) *Changing audiences for industry-supplied pharmaceutical information*. Who is receiving/asking for industry-supplied pharmaceutical information? Is this audience more sophisticated (highly educated) than traditional audiences? What type of comparative information is sought? How is this comparative information utilized and interpreted? What should be FDA's goal in monitoring the communication of comparative drug information to healthcare providers and patients within managed care organizations?

(4) *Changing channels for communication of pharmaceutical information*. What constitutes sufficient evidence of ''independence'' to give

confidence of unbiased decisions in formulary development? How can FDA protect scientific-exchange between the pharmaceutical company and the target audience while protecting the audience from false and misleading pharmaceutical promotion? How should FDA address methods employed by pharmaceutical manufacturers to ''switch'' patients from one drug therapy to another similar product? How should FDA address communications from the PBM's to the target audience? What specific types of information and services do managed health care organizations commonly request from the pharmaceutical industry? Examples of such services may include provider/patient education or formulary coordination between organizations (''pull-through'').

III. Notice of Hearing under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Commissioner of Food and Drugs or his designee. The presiding officer will be accompanied by a panel of Public Health Service employees with relevant expertise.

Persons who wish to participate in the part 15 hearing must file a written notice of participation with the Dockets Management Branch (address above) by September 15, 1995. To ensure timely handling, any outer envelope should be clearly marked with docket number 95N–0228 and the statement ''Pharmaceutical Marketing and Information Exchange in Managed Care Environments.'' Groups should submit two copies of materials. The notice of participation should contain the speaker's name, address, telephone number, affiliation, if any, brief summary of the presentation, and approximate amount of time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. FDA will allocate the time available for the hearing among the persons who file notices of participation as described above. If time permits, FDA may allow interested persons attending the hearing who did not submit a written notice of participation in advance to make an oral presentation at the conclusion of the hearing.

After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by telephone of the time allotted to the person and the approximate time the person's oral presentation is scheduled to begin. The hearing schedule will be available at the hearing. After the hearing, the hearing schedule will be placed on file in the Dockets Management Branch under docket number 95N–0228.

Under § 15.30(f) (21 CFR 15.30(f)), the hearing is informal and the rules of evidence do not apply. The presiding officer and any panel members may question any person during or at the conclusion of their presentation. No other person attending the hearing may question a person making a presentation or interrupt the presentation of a participant.

Public hearings under part 15 are subject to FDA's guideline (21 CFR part 10, subpart C) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings. Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as required by § 15.30(b). Orders for copies of the transcript can be placed at the meeting or through the Dockets Management Branch (address above).

Any handicapped person requiring special accommodations in order to attend the hearing should direct those needs to the contact person listed above.

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing until December 29, 1995.

Dated: August 7, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95–19947 Filed 8–11–95; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[OPL–006–N]

Medicare Program; September 11, 1995 Meeting of the Practicing Physicians Advisory Council

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

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council. This meeting is open to the public.

DATES: The meeting is scheduled for September 11, 1995, from 8 a.m. until 4 p.m. e.d.t. An additional meeting is tentatively scheduled for December 11, 1995.

ADDRESSES: The meeting will be held in Room 800, 8th Floor, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Dr. Samuel Shekar, Executive Director, Practicing Physicians Advisory Council, Room 425–H, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, (202) 260–5463.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act as added by section 4112 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101–508, enacted on November 5, 1990), to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare or Medicaid in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and under served urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before the end of the 2-year term.

The Council held its first meeting on May 11, 1992.

The current members are: Richard Bronfman, DPM., Gary C. Dennis, M.D., Catalina E. Garcia, M.D., Harvey P. Hanlen, O.D., Kenneth D. Hansen, M.D., Ardis Hoven, M.D., Sandral Hullett, M.D., Jerilynn S. Kaibel, D.C., Marie G. Kuffner, M.D., Marc Lowe, M.D., Katherine L. Markette, M.D., Isadore Rosenfeld, M.D., Richard B. Tompkins, M.D., Kenneth M. Viste, Jr., and James C. Waites, M.D. The chairperson is Kenneth M. Viste, Jr. M.D.

The next meeting of the Council will be held on September 11, 1995. The Council agenda will provide for discussion and comment on two items:

- 1996 Physician fee schedule update.
- Notifying beneficiaries of the disposition of provider complaint investigations.

Those individuals or organizations who wish to make 5-minute oral presentations on the above issues should contact the Executive Director by 12:00 noon, August 25, 1995, to be scheduled. A written copy of the oral remarks should be submitted to the Executive Director no later than 12:00 noon, August 25, 1995. For the name, address, and telephone number of the Executive Director, see the **FOR FURTHER INFORMATION CONTACT** section at the beginning of this notice. The number of oral presentations may be limited by the time available.

In addition, Council members will receive a legislative update and be briefed on the Medicaid statewide health care reform demonstrations under section 1115 of the Social Security Act, automated multi-channel laboratory testing, and recent regulatory reforms.

Individuals or organizations may submit written comments on any of the above listed issues to the Executive Director by 12:00 noon, September 1, 1995. The meeting is open to the public, but attendance is limited to the space available on a first-come basis.

(Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Public Law 92–463 (5 U.S.C. App. 2, section 10(a)); 45 CFR Part 11)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 7, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 95–19995 Filed 8–11–95; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. FR–3946–D–01]

Redelegation of Authority

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of redelegation of authority.

SUMMARY: The General Deputy Assistant Secretary for Community Planning and Development is redelegating to the Director, Office of Technical Assistance and Management, the authority to impose sanctions pursuant to 24 CFR Part 24, as to certain enumerated programs.

EFFECTIVE DATE: August 4, 1995.

FOR FURTHER INFORMATION CONTACT: Georjan D. Overman, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street, SW., Room 10251, Washington, DC 20410, telephone (202) 708–4248. A telecommunications device for the hearing-impaired (TDD) is available at (202) 708–0850. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: By delegations of authority dated October 23, 1983 (48 FR 49384), September 4, 1987 (52 FR 33793), June 3, 1988 (53 FR 20563) and August 22, 1994 (59 FR 43132), the Secretary of Housing and Urban Development has delegated to the Assistant Secretary and General Deputy Assistant Secretary for Community Planning and Development the power and authority of the Secretary with respect to certain enumerated programs. This authority includes the authority to impose sanctions on contractors and participants in those programs, pursuant to the provisions of 24 CFR Part 24. See 53 FR 39535 (October 7, 1988) (delegating to all the Assistant Secretaries of HUD the authority to impose sanctions pursuant to 24 CFR Part 24.) In this notice, the General Deputy Assistant Secretary for Community Planning and Development redelegates this authority to impose sanctions pursuant to 24 CFR Part 24, with respect to certain enumerated programs, to the Director, Office of Technical Assistance and Management.

Section A. Authority Redelegated

The General Deputy Assistant Secretary for Community Planning and Development redelegates to the Director, Office of Technical Assistance and Management, Office of Community Planning and Development, the authority to impose sanctions on contractors and participants, pursuant to the provisions of 24 CFR Part 24, for those programs and matters listed below:

1. Title of the Housing and Community Development Act of 1974 (42 U.S.C. 5301), excluding the Work Study Program, under Section 107(c), and the Joint Community Development Program, under Section 107(b)(5).

2. The Urban Homesteading Program under section 810(b), (c), (d), (e), (g) and (h) of the Housing and Community Development Act of 1974 (12 U.S.C. 1706e), excluding the responsibilities delegated specifically to the Assistant Secretary for Housing.

3. The Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (42 U.S.C. 4601.)

4. The Rehabilitation Loan Program under section 312 of the Housing Act of 1964 (42 U.S.C. 1452b), excluding the exercise of powers under section 402(a) of the Housing Act of 1950 (12 U.S.C. 1749(a)), and excluding the responsibilities delegated specifically to the Assistant Secretary for Housing.

5. Community Planning and Development programs no longer authorized for funding until all Departmental responsibilities associated with them are discharged and finally terminated.

6. The Rental Rehabilitation Program under Section 17 of the Housing Act of 1937 (42 U.S.C. 1437o.)

7. The Comprehensive Homeless Assistance Plan, as authorized by Subtitle A of Title IV of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11301 note.)

8. The Emergency Shelter Grants Program as authorized by Subtitle B of Title IV of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11301 note.)

9. Enterprize Zone development as authorized by Title VII of the Housing and Community Development Act of 1987 (42 U.S.C. 11501–11505.)

Section B. No Further Redelegation

The authority redelegated to the Director, Office of Technical Assistance and Management may not be further redelegated pursuant to this delegation.

Authority: Sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: August 4, 1995.

Mark C. Gordon,

General Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 95–19978 Filed 8–11–95; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ-020–7122–00–5499]

Notice of Availability of Draft Environmental Impact Statement (EIS), Proposed Tailings and Waste Rock Disposal Areas, Cyprus Bagdad Copper Corporation, Bagdad, AZ

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Land Management, Phoenix District, in response to a Mining Plan of Operations (MPO) filed by Cyprus Bagdad Copper Corporation (CBCC), is preparing an Environmental Impact Statement (EIS) in compliance with the Federal Land Policy and Management Act of 1976, as amended, 43 CFR 3809, and Section 102(2)(c) of the National Environmental Policy Act of 1969. The proposed action involves development of a new tailings impoundment, expansion of an existing waste rock disposal area, and continuation of expansion of the existing open pit in order to continue copper mining and milling operations in Bagdad, Arizona for 35 years. The proposed action would affect private lands owned by CBCC and approximately 320 acres of public lands administered by the Bureau of Land Management (BLM). Specific written comments are requested on the draft and will be considered in the final EIS.

ADDRESSES/FOR FURTHER INFORMATION, CONTACT: Written comments and requests for copies of the draft EIS should be mailed to: Mary Johnson, Project Manager, Bureau of Land Management, Phoenix District Office, 2015 West Deer Valley Road, Phoenix, AZ 85027, or telephone (602) 780–8090, ext. 564. Copies of the Draft EIS are available for public use/review at the following locations: BLM, Phoenix District Office, 2015 West Deer Valley Road, Phoenix, Arizona 85027; BLM, Kingman Resource Area, 2475 Beverly Ave., Kingman, Arizona 86401; BLM, Arizona State Office, Public Room, 3707 N. 7th St., Suite 300, Phoenix, AZ 85014; Cyprus Bagdad Copper Corporation, Lower Main Street, Environmental Dept., Bagdad, Arizona 86321; Mohave County District Library, 3269 N. Burbank St., Kingman, Arizona; Prescott Public Library, 215 E. Goodwin St., Prescott, Arizona 86303.

DATES: Written comments must be postmarked by October 17, 1995 (or 60 days after the publication date in the **Federal Register** of the Notice of Availability by the Environmental Protection Agency). Public hearings for the Draft EIS will be held at the following times and locations: September 27, 1995, Wednesday, 7:00–9:00 pm, Mohave Community College, Room 106, Kingman, AZ 86401; September 28, 1995, Thursday, 7:00–9:00 pm, Prescott Resort Conference Center, Prescott/Chino Meeting Room), 1500 Highway 69, Prescott, AZ 86301.

Dated: August 8, 1995.

David J. Miller,

Associate District Manager.

[FR Doc. 95–19994 Filed 8–11–95; 8:45 am]

BILLING CODE 4310–32–P

[Docket No. 4310—DN; MT–060–05–1990–01]

Availability of the Draft Environmental Impact Statement for the Zortman and Landusky Mines Reclamation Plan Modifications and Mine Life Extensions, Phillips County, MT

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Notice of availability of the draft environmental impact statement (EIS) for the Zortman and Landusky mines reclamation plan modifications and mine life extensions.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4347), and the Montana Environmental Policy Act, the Bureau of Land Management (BLM) and the Montana Department of Environmental Quality (DEQ), as lead agencies, have prepared, through a third party contractor, a Draft EIS on the impacts of the Zortman Mining, Inc. proposal to expand mining and processing of ore reserves at the Zortman and Landusky mines. The Zortman and Landusky mines are located in southwestern Phillips County about 50 miles south of Malta, Montana, near the southern boundary of the Fort Belknap Indian Reservation.

The Draft EIS presents a preferred alternative and six other alternatives including the company proposed action. The preferred alternative is the agencies' attempt to reduce or avoid the potential environmental impacts of the proposed action. The Draft EIS discloses the possible environmental consequences associated with each alternative.

DATES: Written comments on the Draft EIS will be accepted for 60 days following the date the Environmental Protection Agency publishes the Notice of Filing of the draft in the **Federal Register**.

Comments can also be presented at four open houses/public meetings to be held in: Lodgepole, Montana, September 18, 1995, at the Medicine Bear Lodge; Hays, Montana, September 19, 1995, at the John Capture Center; Malta, Montana, September 20, 1995, at the Guard Armory; and Landusky, Montana, September 21, 1995, at the Community Hall. All of these open houses/public meetings will begin at 5:00 p.m. with an open house to answer questions followed at 7:30 p.m. by a meeting to accept comments. These meetings will also be the forum for the U.S. Army Corps of Engineers to collect public comments on the Zortman Mining, Inc. 404 permit application for the Zortman and Landusky mine expansions.

ADDRESSES: Written comments should be addressed to David L. Mari, District Manager, Bureau of Land Management, Lewistown District Office, P.O. Box 1160, Lewistown, Montana 59457–1160.

Copies of the Draft EIS will be available from the Bureau of Land Management, Lewistown District Office, P.O. Box 1160, Lewistown, Montana 59457–1160 (406–538–7461) or the Montana Department of Environmental Quality, Hard Rock Bureau, P.O. Box 201601, Helena, Montana 50620–1601 (406–444–2074). Public reading copies will be available for review at the following locations: Bureau of Land Management, Office of External Affairs, Main Interior Building, Room 5600, 18th and C Streets NW, Washington, DC; Bureau of Land Management, External Affairs Office, Montana State Office, 222 North 32nd Street, Billings, Montana; Bureau of Land Management, Lewistown District Office, Airport Road, Lewistown, Montana; Bureau of Land Management, Phillips Resource Area, 501 South 2nd St East, Malta, Montana; and State of Montana, Department of Environmental Quality, 1625 11th Ave, Helena, Montana.

FOR FURTHER INFORMATION CONTACT: Jim Robinson, Team Leader, Montana Department of Environmental Quality, Hard Rock Bureau, P.O. Box 201601, Helena, Montana 59620–1601 (406–444–2074) or Scott Haight, Team Leader, Bureau of Land Management, Lewistown District Office, P.O. Box 1160, Lewistown, Montana 59457–1160 (406–538–7461).

SUPPLEMENTARY INFORMATION: On May 11, 1992, Zortman Mining, Inc. (ZMI) filed an application with the Bureau of Land Management, Lewistown District Office, and the Montana Department of State Lands (part of the Montana Department of Environmental Quality as of July 1, 1995), to expand mining operations at the Zortman Mine in the Little Rocky Mountains, Montana. The proposal includes: expansion of existing mine pits to access sulfide ore; a 150-acre, 60-million ton waste rock disposal area; crushing facilities; a 2.5-mile conveyor system; a 200-acre, 80-million ton capacity leach pad; a new processing plant and ponds; a limestone quarry; and other associated facilities. Total disturbance would increase from the existing 401 acres to about 1,292 acres. The operation is located on private and public land. Issues include Native American religious concerns, acid rock drainage, reclamation, and socioeconomic.

In a March 9, 1994, Decision Record, the BLM and DEQ included the analysis of acid rock drainage corrective measures for the nearby Landusky Mine within the scope of the EIS for the Zortman Mine expansion, since acid rock drainage has been a problem at both mines. The draft EIS addresses additional mining at the Landusky and Zortman mines, as well as modified reclamation plans for both facilities to address acid rock drainage.

Public participation has occurred throughout the EIS process. A Notice of Intent was published in the **Federal Register** in November 1992 followed by a supplemental notice in April 1994 expanding the scope of the EIS for the Landusky Mine. Since that time, public meetings and informational mailings were conducted to solicit comments for the scope of the EIS. Any comments presented throughout the process have been considered.

Dated: August 2, 1995.

B. Gene Miller,

Associate District Manager.

[FR Doc. 95–19953 Filed 8–11–95; 8:45 am]

BILLING CODE 1430–DN–P

Colorado; Front Range Resource Advisory Council, Northwest Resource Advisory Council, Southwest Resource Advisory Council; Meetings

AGENCY: Bureau of Land Management, Interior.

ACTION: Resource Advisory Councils—Notice of Meeting.

SUMMARY: The three Resource Advisory Councils for the State of Colorado, the Front Range Resource Advisory Council, the Northwest Resource Advisory Council, and the Southwest Resource Advisory Council, will meet at the Grand Junction Hilton, 743 Horizon Drive, Grand Junction, Colorado 81506, beginning on Tuesday, August 22 at 10:30 AM, and ending on August 22 at 3:30 PM. The entire meeting is open to the public. Individuals who plan to attend and need further information about the meeting, or need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the individual listed below, under **FOR FURTHER INFORMATION CONTACT,** at least 5 days prior to the meeting.

DATES: The meeting will be held on Tuesday, August 22, 1995, from 10:30 AM to 3:30 PM.

ADDRESSES: The meeting will be held at the Grand Junction Hilton, 743 Horizon Drive, Grand Junction, Colorado 81506.

SUPPLEMENTARY INFORMATION: The purpose of this notice is to announce the specific time and place of the joint meeting of the 3 Colorado Resource Advisory Councils, which were announced in a **Federal Register** notice of August 7, 1995 (60FR 40191). The meeting will be held on August 22, 1995, in Grand Junction, Colorado, to discuss the operation, organization, and general goals of the Councils. The 3 Resource Advisory Councils are being established in accordance with the provisions of the Federal Advisory Committee Act of 1972 (FACA) 5 U.S.C. App. These councils are the Front Range Resource Advisory Council, the Northwest Resource Advisory Council, and the Southwest Resource Advisory Council. These councils will be created by the filing of their charters with the appropriate congressional committees and the Library of Congress on August 21, 1995. The councils are being established to provide advice to the Secretary of the Interior concerning the problems relating to land use planning and the management of public lands within the area for which the advisory councils are established. The councils will provide representative counsel and advice to BLM on the planning and management of the public lands as well as advice on other public land resource issues. Council members will be residents of Colorado and will be appointed by the Secretary.

FOR FURTHER INFORMATION CONTACT: Sherri Bell, Colorado State Office, Bureau of Land Management, 2850 Youngfield Street, Lakewood, Colorado 80215–7076. (303) 239–3670.

Dated: August 9, 1995.

Nina Rose Hatfield,

Acting Deputy Director.

[FR Doc. 95–20036 Filed 8–11–95; 8:45 am]

BILLING CODE 4310–84–P

[AZ–020–05–1430–01; AZA 7666 and AZA 22627]

Arizona: Termination of R&PP Classification and Segregation in Apache and Pinal Counties; Opening Order in Pinal County, AZ

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: This notice will terminate the R&PP classification and segregation on 87.43 acres and open 7.43 acres to mineral leasing.

EFFECTIVE DATE: August 14, 1995.

FOR FURTHER INFORMATION CONTACT: Jim Andersen, Realty Specialist, Phoenix District Office, 2015 West Deer Valley Road, Phoenix, Arizona 85027. Telephone (602) 780–8090.

SUPPLEMENTARY INFORMATION: The following described lands were classified and segregated under the provisions of the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 *et seq.*). Since they are no longer needed for the purpose classified, the classification and segregation for the following described lands will be terminated upon publication of this notice:

(1) *AZA 7666.* The following described land was segregated from the public land laws and mining and mineral leasing laws. Upon publication, the land will be open to mineral leasing. It will remain withdrawn from the public land laws and the mining laws under Power Site Classification 438 and PLO 3835, Middle Gila River Project:

Gila and Salt River Meridian, Arizona

T. 4 S., R. 13 E.,
Sec. 12, metes-and-bounds description in lots 1 and 3, (formerly described as a parcel of land situated in the NE¼NE¼).
Containing 7.43 acres.

(2) *AZA 22627.* The following described land was segregated from the public land laws and mining laws. It will remain withdrawn from these laws under Public Water Reserve No. 55, Arizona No. 9.

Gila and Salt River Meridian, Arizona

T. 11 N., R. 28 E.,
Sec. 18, N½SE¼.
Containing 80 acres.

Dated: August 3, 1995.

Evelyn Stob,

Acting Chief, Lands and Minerals Operations Section.

[FR Doc. 95–19970 Filed 8–11–95; 8:45 am]

BILLING CODE 4310–32–P

Fish and Wildlife Service

Availability of an Environmental Assessment and Receipt of an Application for an Incidental Take Permit for the Endangered Delhi Sands Flower-Loving Fly for the Proposed Colton Transmission Line and Substation Project in the City of Colton, San Bernardino County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: The U.S. Fish and Wildlife Service (Service) has under consideration a proposal to issue a 10-year permit under Section 10(a)(1)(B) of the Endangered Species Act (ESA) that would authorize incidental taking of the endangered Delhi Sands flower-loving fly (*Rhaphiomidas terminatus abdominalis*). The applicant for this incidental take permit is the City of Colton, California. The application is accompanied by a proposed Habitat Conservation Plan (HCP) for the Delhi Sands flower-loving fly and an Implementing Agreement. In response to the permit application and the accompanying proposal, an Environmental Assessment (EA) has been prepared pursuant to the National Environmental Policy Act (NEPA). This notice is provided pursuant to section 10 of the ESA and NEPA regulations (40 CFR 1506.6).

The Service will evaluate the application, associated documents, and comments submitted thereon to determine whether the application meets the requirements of NEPA regulations and section 10(a) of the ESA. If it is determined that the requirements are met, a permit will be issued for the incidental take of the Delhi Sands flower-loving fly. The final NEPA and permit determination will be made no sooner than 30 days from the date of this notice. This notice describes the currently proposed action and alternatives, and solicits comments on the complete permit application, as well as the issues and alternatives raised in the EA. All comments received, including names and addresses, will become part of the official administrative record and may be made available to the public.

DATES: Written comments related to the Service's EA and the City of Colton's permit application, HCP, and IA, should be received by the Service on or before September 13, 1995.

ADDRESSES: Information, comments, or questions regarding the EA, permit application, HCP, and IA, should be submitted to Mr. Gail Kobetich, Field Supervisor, U.S. Fish and Wildlife Service, 2730 Loker Avenue West, Carlsbad, California 92008. Written comments also may be sent by facsimile to (619) 431–9618.

FOR FURTHER INFORMATION CONTACT: Mr. Pete Sorensen, Assistant Field Supervisor, at the above Carlsbad address, telephone (619) 431–9440. Individuals wishing copies of the EA, HCP, IA, and/or permit application should immediately contact Mr. Sorenson. Persons wishing to review background material may obtain it by contacting the City of Colton, telephone (909) 370–5079. Documents also will be available for public inspection by appointment during normal business hours (8 am to 5 pm, Monday through Friday) at the Service's Carlsbad Field Office (see **ADDRESSES** section above).

SUPPLEMENTARY INFORMATION: The Service listed the Delhi Sands flower-loving fly as an endangered species on September 23, 1993 (58 FR 49881). As an endangered species, the Delhi Sands flower-loving fly is protected pursuant to Section 9 of the ESA against take; that is, no one may harass, harm, pursue, hunt, shoot, wound, kill, trap, capture or collect the species, or attempt to engage in such conduct (16 USC 1538). However, under certain circumstances, the Service may issue permits to take endangered wildlife species incidental to, and not the purpose of, otherwise lawful activities. Regulations governing permits for endangered species are at 50 CFR 17.22.

The City of Colton proposes to construct a transmission line and substation project located in the City of Colton, in San Bernardino County. The proposed project is partially located in undeveloped areas that are either known to support the endangered Delhi Sands flower-loving fly or are considered suitable habitat for the species. Pole placement, and construction of the substation and a portion of the access road, would result in the permanent loss of 2.4 acres of suitable Delhi Sands flower-loving fly habitat. In addition, construction of the transmission line, underground distribution line, and portions of the substation and access road would result in the temporary disturbance of 2.2 acres of occupied and potential habitat. Operation and maintenance activities of the proposed substation and transmission lines (e.g., driving to and from the facility and regularly scheduled cleaning of the transmission lines) also may result in additional take of endangered species remaining on or adjacent to the proposed project site.

Two listed plant species, Santa Ana River woolly-star (*Eriastrum densifolium* ssp. *sanctorum*) and slender-horned spineflower (*Dodecahema leptoceras*), are known to occur within or near the proposed transmission line and substation. Although no incidental take authorization is required for listed plant species, impacts to these species must be addressed in the intra-Service consultation required pursuant to section 7(a) of the ESA.

The City of Colton proposes to mitigate for this incidental take by implementing several on-site and off-site mitigation measures. Such measures include: off-site acquisition and management of 7.5 acres; funding a $66,250 endowment for maintenance and enhancement of the 7.5-acre site; conducting pre-construction surveys in occupied Delhi Sands flower-loving fly habitat to determine pole placement and access routes that avoid and minimize direct impacts to the species; conducting pre-construction surveys to determine pole placement and access routes that avoid impacts to listed plant species; and restoration of temporary disturbance areas, and various additional on-site measures to be undertaken during construction and operation of their facility.

In addition to the proposed project and no project alternatives, the City of Colton considered six other alternative sites for the substation with different routes for the transmission lines. Alternative sites and routes were rejected for the following reasons: Site drainage characteristics; earthwork requirements; distance from electrical load centers; flood potential; poor access; and/or high visibility impacts. Selection of a new alternative site would delay start-up of the San Bernardino County hospital indefinitely and would be financially infeasible for the project applicant.

Dated: August 3, 1995.

Thomas Dwyer,

Deputy Regional Director, Region 1, Portland, Oregon.

[FR Doc. 95–19993 Filed 8–11–95; 8:45 am]

BILLING CODE 4310–55–P

Aquatic Nuisance Species Task Force Meeting

AGENCY: Fish and Wildlife Service, Department of the Interior.

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting of the Aquatic Nuisance Species Task Force. A number of subjects will be discussed during the meeting including: Reauthorization of the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990, ballast water management activities/legislation, Ruffe Control Program, Brown Tree Snake Control Program, pilot black carp risk assessment, and upcoming events.

DATES: The ANS Task Force will meet from 9 a.m. to 3 p.m. on Thursday, August 31, 1995.

ADDRESSES: The ANS Task Force meeting will be held at the U.S. Fish and Wildlife Building, Room 200AB, 4401 N. Fairfax Drive, Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: Jay Troxel, ANS Task Force Coordinator, U.S. Fish and Wildlife Service, telephone (703) 358–1718.

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. I), this notice announces a meeting of the Aquatic Nuisance Species Task Force established under the authority of the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 (Pub. L. 101–646, 104 Stat. 4761, 16 U.S.C. 4701 et seq., November 29, 1990). Minutes of the meetings will be maintained by the Coordinator, Aquatic Nuisance Species Task Force, Room 840, 4401 North Fairfax Drive, Arlington, Virginia 22203 and will be available for public inspection during regular business hours, Monday through Friday within 30 days following the meeting.

Dated: August 7, 1995.

Gary Edwards,

Assistant Director, Fisheries, Co-Chair, Aquatic Nuisance Species Task Force.

[FR Doc. 95–19948 Filed 8–11–95; 8:45 am]

BILLING CODE 4310–55–M

Minerals Management Service

Information Collection Submitted to the Office of Management and Budget (OMB) for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to OMB for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collections of information and related forms may be obtained by contacting the Bureau's Clearance Officer at the telephone number listed below. Comments and suggestions on the proposal should be made directly to the Bureau Clearance Officer and to the Office of Management and Budget; Paperwork Reduction Project (1010–0018); Washington, D.C. 20503, telephone (202) 395–7340, with copies to Chief, Engineering and Standards Branch; Mail Stop 4700; Minerals Management Service; 381 Elden Street; Herndon, Virginia 22070–4817.

Title: Request for Reservoir Maximum Efficient Rate (MER), Form MMS–127

OMB approval number: 1010–0018

Abstract: Respondents submit Form MMS–127 to the Minerals Management Service's (MMS) Regional Supervisors so they can determine whether a lessee has correctly classified an oil or gas reservoir and whether the reservoir MER requested by the lessee is valid

Bureau form number: Form MMS–127

Frequency: On occasion

Description of respondents: Federal OCS oil and gas lessees

Annual burden hours: 910

Bureau Clearance Officer: Arthur Quintana, (703) 787–1239

Dated: July 28, 1995.

E.P. Danenberger,

Acting Deputy Associate Director for Operations and Safety Management.

[FR Doc. 95–19969 Filed 8–11–95; 8:45 am]

BILLING CODE 4310–MR–M

National Park Service

Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects From the State of Texas in the Possession of the Fort Hood Archeological Laboratory

AGENCY: National Park Service, Interior

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003(d), of the completion of the inventory of human remains and associated funerary objects in the curation facility of the Directorate of Public Works at Fort Hood, TX from five sites in the state of Texas.

A detailed inventory and assessment of these remains has been made by the staff archeologist at Fort Hood in consultation with representatives of the Comanche Tribe of Oklahoma and the Tonkawa tribe of Oklahoma. Copies of this inventory have also been sent to the Apache Tribe of Oklahoma, the Wichita and Affiliated Tribes, the Caddo Indian Tribe of Oklahoma and the Kiowa Tribe.

The partial and fragmentary human remains of 48 individuals were recovered in 1985 from a vandalized burial ground at Javalina shelter in Bell County, Texas. A total of 1,214 bones and fragments were recovered from the surface where they had been discarded by vandals. Inventory and examination of the remains established that the partial remains of 20 adults, ten adolescents, nine children and nine infants were present. Sex of the remains could not be determined. No known individuals were identified. Artifacts recovered from the site with the remains included a flake of obsidian and debitage of local cherts.

This site has been identified as being within the Comanche's traditional occupation area based on the abnormal number of juvenile remains, suggesting a historical disease epidemic, evidence of access to obsidian, the Comanche occupation of Central Texas in historic times, and consultation with the Comanche Tribe. Based on the above mentioned information, officials of the Fort Hood Archeological Laboratory have determined that, pursuant to 25U.S.C. 3001(2), there is a relationship of shared group identity which can be reasonably traced between these human remains and associated funerary objects and the Comanche Tribe. Officials of the Fort Hood Archeological Laboratory have also determined that the artifacts are reasonably believed to have been placed with individual human remains either at the time of death or later as a part of a death rite or ceremony of a culture, pursuant to 25 U.S.C. 3001 (3)(A).

On November 22, 1991 the above human remains and associated funerary objects were repatriated to the Reverend John Pahdocony of the Comanche Cemetery Committee on behalf of the Comanche Tribal Council.

The partial and fragmentary remains of a one adult individual were collected in 1986 from an erosional gully on the bank of the Leon River near Fort Griffin, Bell County, Texas. The remains eroded from the bank of the Leon River near a dark and dense midden deposit from an open campsite on the flood plain. The sex of the individual could not be determined. No known individual was identified.

This site has been identified as being within the Comanche's traditional occupation area, based on consultation

with representatives of the Comanche Tribe and written historic records.

Officials of the Fort Hood Archeological Laboratory have determined that, pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity which can be reasonably traced between these human remains and the Comanche Tribe.

On November 22, 1992 the above mentioned human remains were repatriated to Phillip R. Narcomey of the Comanche Cemetery Committee on behalf of the Comanche Tribal Council.

The partial and fragmentary remains of a one adult individual were collected in 1992 from the surface of a vandalized burial site (41BL0844). The remains consist of nine bone fragments. No known individual was identified.

This site has been identified as being within the Comanche's traditional occupation area, based on consultation with representatives of the Comanche Tribe and written historic records.

Officials of the Fort Hood Archeological Laboratory have determined that, pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity which can be reasonably traced between these human remains and the Comanche Tribe.

On November 21, 1993 the above mentioned human remains were repatriated to Phillip R. Narcomey of the Comanche Cemetery Committee on behalf of the Comanche Tribal Council.

The partial and fragmentary human remains of six individuals were recovered during the summer of 1990 from a rockshelter site (41BL671) on Fort Hood, by a field school conducted by Texas A&M University. Inventory and examination of the remains established that the remains of two adult males, one adult female, one child between the ages of 6 and 10 years, one new-born child, and an individual whose age and sex could not be determined. Artifacts recovered elsewhere in the site suggested it was occupied by peoples of the Toyah and Austin Foci, acknowledged as ancestral to the Tonkawa Tribe. No known individuals were identified.

This site has been identified as being within the Tonkawa's aboriginal occupation area based on the oral traditions of the Tonkawa tribe and historic accounts of their occupations in central Texas through consultations with representatives of the Tonkawa Tribe of Oklahoma. Officials of the Fort Hood Archeological Laboratory have determined that, pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity which can be reasonably traced between these human remains and the Tonkawa Tribe who are generally acknowledged to have occupied the Bell County area of central Texas before the arrival of the Comanche in the eighteenth century.

On November 20, 1994 the above six human remains were repatriated to Ms. Virginia Combrink, President of the Tonkawa Tribe of Oklahoma on behalf of that Tribe.

Between 1984 and February 25, 1986, 78 fragments of human bone representing four individuals were collected from rockshelter site (41BL0069) on Fort Hood, by a field party from Texas A&M University. Inventory and examination of the remains established that the remains of two adult individuals, one adolescent, and one child between the ages of 6 and 10 years, sex could not be determined. Artifacts recovered elsewhere in the site suggested it was occupied by prehistoric peoples of the Toyah and Austin Foci. No known individuals were identified.

This site has been identified as being within the Tonkawa's aboriginal occupation area based on the oral traditions of the Tonkawa tribe and historic accounts of their occupations in central Texas through consultations with representatives of the Tonkawa Tribe of Oklahoma. Officials of the Fort Hood Archeological Laboratory have determined that, pursuant to 25U.S.C. 3001(2), there is a relationship of shared group identity which can be reasonably traced between these human remains and the Tonkawa Tribe who are generally acknowledged to have occupied the Bell County area of central Texas before the arrival of the Comanche in the eighteenth century.

During the 1978 recording of 41CV0130 on Fort Hood a single fragment of a human adult femur was recovered from surface spoil. 41CV0130 also yielded evidence of occupation during the late archaic period.

This site has been identified as being within the Tonkawa's aboriginal occupation area based on the oral traditions of the Tonkawa tribe and historic accounts of their occupations in central Texas through consultations with representatives of the Tonkawa Tribe of Oklahoma. Officials of the Fort Hood Archeological Laboratory have determined that, pursuant to 25U.S.C. 3001(2), there is a relationship of shared group identity which can be reasonably traced between these human remains and the Tonkawa Tribe who are generally acknowledged to have occupied the Bell County area of central Texas before the arrival of the Comanche in the eighteenth century.

This notice has been sent to officials of the Tonkawa tribe of Oklahoma, The Comanche Tribe, the Wichita and Affiliated Tribes, the Caddo Tribe of Oklahoma, the Kiowa Tribe and the Apache Tribe. Representatives of any other Indian tribe which believes itself to be culturally affiliated with these human remains should contact Dr. Jack M. Jackson, Fort Hood Staff Archeologist, HQ III Corps and Fort Hood, attn: AFZF-PW-ENV, Fort Hood, Texas 76544–5057; telephone (817) 287–7965, before September 13, 1995. Repatriation of the human remains from sites 41BL0069 and 41CV0130 may begin after that date if no additional claimants come forward.

Dated: August 7, 1995

Francis P. McManamon

Departmental Consulting Archeologist

Chief, Archeological Assistance Division

[FR Doc. 95–19958 Filed 8–11–95; 8:45 am]

BILLING CODE 4310–70–F

DEPARTMENT OF JUSTICE

Information Collections Under Review

The Office of Management and Budget (OMB) has been sent the following collection(s) of information proposals for review under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35) and the Paperwork Reduction Reauthorization Act since the last list was published. Entries are grouped into submission categories, with each entry containing the following information:

(1) The title of the form/collection;

(2) The agency form number, if any, and the applicable component of the Department sponsoring the collection;

(3) Who will be asked or required to respond, as well as a brief abstract;

(4) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond;

(5) An estimate of the total public burden (in hours) associated with the collection; and,

(6) An indication as to whether section 3504(h) of Pub. L. 96–511 applies.

Comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the OMB reviewer, Mr. Jeff Hill on (202) 395–7340 and to the Department of Justice's Clearance Officer, Mr. Robert B. Briggs, on (202) 514–4319. If you anticipate commenting on a form/collection, but find that time to prepare such comments will prevent you from prompt submission, you should notify the OMB reviewer and the Department

of Justice Clearance Officer of your intent as soon as possible. Written comments regarding the burden estimate or any other aspect of the collection may be submitted to Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, and to Mr. Robert B. Briggs, Department of Justice Clearance Officer, Systems Policy Staff/ Information Resources Management/ Justice Management Division, Suite 850, WCTR, Washington, DC 20530.

Revision of a Currently Approved Collection

(1) Application—Inspections Facilitation Program.

(2) Form I–823, I–832A, I–823B, I–823C, and I–823D. Immigration and Naturalization Service. United States Department of Justice.

(3) Primary: Individuals or households. Other: None. The information collected will be used to determine eligibility for automated inspections programs and to secure those data elements necessary to confirm enrollment at the time of application for admission to the United States.

(4) 500,000 annual respondents .5 hours per response.

(5) 250,000 annual burden hours.

(6) Not applicable under section 3504(h) of Pub. L. 96–511.

Public comment on this item is encouraged.

Dated: August 8, 1995.

Kathleen T. Albert,

Acting Department Clearance Officer, United States Department of Justice.

[FR Doc. 95–19950 Filed 8–11–95; 8:45 am]

BILLING CODE 4410–10–M

Drug Enforcement Administration

[Docket No. 95–3]

Habit Management Institute, Inc.; Denial of Application

On October 31, 1994, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Habit Management Institute, Inc., of Manchester, New Hampshire (Respondent), proposing to deny its application for DEA registration as a Narcotic Treatment Program (NTP) under 21 U.S.C. 823(g). The statutory basis for the Order to Show Cause was that Respondent was not authorized to dispense controlled substances in the State of New Hampshire, the state in which it proposed to operate.

Respondent, through counsel, requested a hearing on the issues raised in the Order to Show Cause, and the matter was docketed before Administrative Law Judge Paul A. Tenney. On December 16, 1994, the Government filed a motion for summary disposition clarifying the Order to Show Cause and alleging, *inter alia*, that Respondent was not authorized to handle controlled substances in the State of New Hampshire, and, that Respondent lacked authority from the Food and Drug Administration of the Department of Health and Human Services (FDA), to operate an NTP. The Government's motion was supported by a letter from an FDA official informing Respondent that because the State of New Hampshire had denied its application to establish an NTP, the FDA was unable to approve its application. Respondent did not file a response to the Government's motion and did not deny that FDA has denied its application.

On January 30, 1995, the administrative law judge issued his conclusions of law and recommended ruling, recommending that Respondent's application for a DEA Certificate of Registration as an NTP be denied. On March 9, 1995, the administrative law judge transmitted the record to the Deputy Administrator. After a careful consideration of the record in its entirety, the Deputy Administrator, pursuant to 21 CFR 1316.67, enters his final order in this matter, based on the conclusions of law set forth herein.

Practitioners who dispense narcotic drugs as part of a maintenance treatment or detoxification treatment are required to obtain a separate DEA registration under 21 U.S.C. 823(g). Authorization from the FDA is a prerequisite to the granting of registration by DEA. 21 U.S.C. 823(g)(1). The administrative law judge found that FDA notified Respondent, in writing, that the FDA had not approved Respondent's NTP.

DEA does not have statutory authority under the Controlled Substances Act to register an NTP unless that entity is authorized by the FDA to dispense controlled substances. 21 U.S.C. 823(g). In a proceeding to obtain registration as an NTP, if the applicant does not possess the requisite FDA authorization to operate an NTP, a motion for summary disposition is properly entertained. *Rosalind A. Cropper, Inc.,* 60 FR 18143 (1995). It is well settled that where no question of fact exists, or where the material facts are agreed, a plenary administrative proceeding is not required. *Phillip E. Kirk, M.D.,* 48 FR 32887 (1983), aff'd sub nom, *Kirk* v. *Mullen,* 749 F.2d 297 (6th Cir. 1984).

Accordingly, the Deputy Administrator adopts the conclusions of law and recommended ruling of the administrative law judge in its entirety. Based on the foregoing, the Deputy Administrator of the Drug Enforcement Administration, pursuant to 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that Respondent's application for DEA Certificate of Registration as an NTP be, and it hereby is, denied. This order is effective September 13, 1995.

Dated: August 7, 1995.

Stephen H. Greene,

Deputy Administrator.

[FR Doc. 95–19956 Filed 8–11–95; 8:45 am]

BILLING CODE 4410–09–M

[Docket No. 95–19]

Derrick K. Mobley, M.D.; Revocation of Registration

On December 14, 1994, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Derrick K. Mobley, M.D. of Philadelphia, Pennsylvania (Respondent), proposing to revoke his DEA Certificates of Registration, BM2550829, issued to him in Pennsylvania, and BM1810109, issued to him in New Jersey, and deny any pending applications for registration as a practitioner. The statutory basis for the Order to Show Cause was that Respondent's continued registration as a practitioner is not consistent with the public interest and that Respondent is no longer authorized to handle controlled substances in the Commonwealth of Pennsylvania or the State of New Jersey. 21 U.S.C. 823(f) and 21 U.S.C. 824(a)(3).

Respondent, *pro se*, requested a hearing on the issues raised in the Order to Show Cause, and the matter was docketed before Administrative Law Judge Mary Ellen Bittner. On March 9, 1995, the Government filed a motion for summary disposition alleging that Respondent was not authorized to handle controlled substances in either New Jersey or Pennsylvania, the jurisdictions in which he proposes to practice. Respondent did not file a response to the Government's motion, and did not deny that he had surrendered his New Jersey license and that his Pennsylvania license had been revoked. No evidentiary hearing was held on this matter as no questions of fact were to be resolved, only a question of law.

On May 15, 1995, the administrative law judge issued her opinion and

recommended decision, recommending that Respondent's DEA Certificates of Registration be revoked. No exceptions were filed by either party. On June 22, 1995, the administrative law judge transmitted the record to the Deputy Administrator. After a careful consideration of the record in its entirety the Deputy Administrator enters his final order in this matter, in accordance with 21 CFR 1316.67, based on conclusions of law as set forth herein.

Respondent voluntarily surrendered his license to practice medicine in New Jersey effective January 28, 1993. As part of the consent order signed with the New Jersey State Board of Medical Examiners (New Jersey Board), Respondent was ordered to deliver to the New Jersey Board his State and Federal controlled substances registrations. On December 28, 1994, the Commonwealth of Pennsylvania, Bureau of Professional and Occupational Affairs, State Board of Medicine, issued an order revoking Respondent's license to practice medicine and surgery. Respondent did not deny that he was no longer authorized to handle controlled substances in Pennsylvania or New Jersey.

The DEA has consistently held that it does not have statutory authority under the Controlled Substances Act to register a practitioner unless that practitioner is authorized to dispense controlled substances by the state in which he proposes to practice. *See Lawrence R. Alexander, M.D.*, 57 FR 22256 (1992); *Bobby Watts, M.D.*, 53 FR 11919 (1988); *Robert F. Witek, D.D.S.*, 52 FR 4770 (1987). In such cases a motion for summary disposition is properly entertained. There is no need for a plenary evidentiary hearing since there are no questions of fact to be resolved by such a hearing. *Phillip E. Kirk, M.D.*, 48 FR 32887 (1983), aff'd sub nom, *Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984); *Floyd A. Santner, M.D.*, 47 FR 51831 (1982). The administrative law judge found that, where Respondent is not currently authorized to practice medicine or perform surgery in either New Jersey or Pennsylvania, it is reasonable to infer, and Respondent did not deny, that he also is not authorized to handle controlled substances. Therefore, because Respondent is no longer authorized to handle controlled substances in the Commonwealth of Pennsylvania or the State of New Jersey, the Deputy Administrator cannot permit him to maintain DEA Certificates of Registration in those jurisdictions.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificates of Registration BM2550829 and BM1810109, previously issued to Derrick K. Mobley, M.D., be, and they hereby are, revoked, and that any outstanding applications for renewal of such registrations be, and they hereby are, denied, This order is effective September 13, 1995.

Dated: August 8, 1995.

Stephen H. Greene,

Deputy Administrator.

[FR Doc. 95–20020 Filed 8–11–95; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Employment and Training Administration

Proposed Information Collection Request Submitted for Public Comment and Recommendations; Evaluation of Worker Profiling and Reemployment Services Systems; Survey of State Administrators

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA 95). This program helps to ensure that requested data can be provided in the desired format, reporting burden is minimized, reporting forms are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration is soliciting comments concerning the proposed new collection of the Survey of State Administrators for the Evaluation of Worker Profiling and Reemployment Services Systems. A copy of the proposed information collection request can be obtained by contacting the employee listed below in the contact section of this notice.

DATES: Written comments must be submitted on or before October 13, 1995. If you anticipate that you will be submitting written comments, but find it difficult to do so within the period of time allowed by this notice, you should request an extension from the contact listed below as soon as possible. An effort will be made to try to accommodate each request, unless otherwise justified.

FOR FURTHER INFORMATION CONTACT: Jon Messenger, U.S. Department of Labor, Employment and Training Administration, Unemployment Insurance Service, Room S–4519, 200 Constitution Avenue, N.W., Washington, D.C. 20210, (202) 219–5608.

SUPPLEMENTARY INFORMATION:

I. Background

The U.S. Department of Labor, Employment and Training Administration (ETA), has undertaken a major initiative to help the State implement effective Worker Profiling and Reemployment Services Systems, as required by the Unemployment Compensation Amendments of 1993, Public Law (P.L.) 103–152. The major goal of the WPRS initiative is to assist those unemployment insurance (UI) claimants who are at greatest risk of becoming unemployed to become reemployed by quickly referring them to reemployment services tailored to their individual needs.

ETA is conducting a comprehensive evaluation of the Worker Profiling and Reemployment Services (WPRS) initiative. This effort is designed to provide both:

(1) An evaluation of the operation and effectiveness of State WPRS systems, in accordance with P.L. 103–152, which mandates a report to the Congress by November 24, 1996, and

(2) A longer-range evaluation to provide an assessment of the operation and effectiveness of more mature State WPRS systems.

This Survey of State Administrators will obtain data for an implementation and process analysis of State WPRS systems. The survey will provide in-depth knowledge of each State's approach to implementing their WPRS system. This survey will also provide the data necessary for identifying distinct groupings or modes of States' operational approaches to Worker Profiling and Reemployment Services, which will be used in the effectiveness portion of the WPRS evaluation to compare the relative effectiveness different implementation approaches.

II. Current Actions

ETA proposes to conduct a Survey of State Administrators involved in designing and implementing WPRS systems. This includes administrators from the Unemployment Insurance (UI), Employment Service (ES), and Economic Dislocation and Worker Adjustment Assistance (EDWAA) programs. Within basic Federal guidelines, individual States have great

latitude in designing their WPRS systems. This survey will systematically gather information about how States have designed their WPRS systems—the policies and procedures adopted, and the process by which this occurred—and their progress to date in implementing these systems.

Written comments on the survey questionnaire should address the accuracy of the burden estimates and ways to minimize burden, including the use of automated collection techniques or the use of other forms of information technology.

Type of Review: New
Agency: Employment and Training Administration
Title: Survey of State Administrators
Frequency: Twice (once in Calendar Year 1996, once in Calendar Year 1997)
Affected Public: State Government
Number of Respondents: 159 (53 States and jurisdictions times 3 administrators each)
Estimated Time Per Respondent: For 106 of the respondents, the time burden will be 7 minutes each. For 53 respondents, the time burden will be 27 minutes each (those administrators responsible for coordinating the WPRS Initiative in the State or jurisdiction will need to complete a more comprehensive questionnaire)
Total Burden Hours: 72 (2 waves of surveys, 36 hours per wave)

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Signed at Washington, D.C., this 8th day of August, 1995.

Robert O. Deslongchamps,

Acting Director, Unemployment Insurance Service.

[FR Doc. 95–19998 Filed 8–11–95; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF JUSTICE

Office of Justice Programs

National Institute of Justice

[OJP (NIJ) No. 1059]

RIN 1121–ZA21

National Institute of Justice ''Solicitation for the Review of External DNA Proficiency Testing''

AGENCY: U.S. Department of Justice, Office of Justice Programs, National Institute of Justice.

ACTION: Announcement of the availability of the National Institute of Justice's ''Solicitation for the Review of External DNA Proficiency Testing''.

ADDRESSES: National Institute of Justice, 633 Indiana Avenue, NW., Washington, D.C. 20531.

DATES: The deadline for receipt of proposals is close of business on September 8, 1995.

FOR FURTHER INFORMATION CONTACT: Richard Rau, National Institute of Justice, at (202) 514–6206.

SUPPLEMENTARY INFORMATION: The following supplementary information is provided:

Authority

This action is authorized under the Omnibus Crime Control and Safe Streets Act of 1968, §§ 201–03, as amended, 42 U.S.C. 3721–23 (1988).

Background

Through this solicitation the National Institute of Justice is seeking to review the state-of-the-science in blind and open external DNA proficiency testing for forensic and nonforensic (medical, chemical, and biological) laboratories. In addition, this solicitation seeks the development of criteria for model external DNA proficiency testing. NIJ is directed by the DNA Act of 1994 to report to Congress on the state of availability of a blind DNA proficiency testing program for the field. Interested persons should call the National Criminal Justice Reference Service (NCJRS) at 1–800–851–3420 to obtain a copy of ''Solicitation for the Review of External DNA Proficiency Testing'' (refer to document No. SL000133). The solicitation is available electronically via the NCJRS Bulletin Board, which can be accessed via Internet. Telnet to ncjrsbbs.aspensys.com, or gopher to ncjrs.aspensys.com 71. Those without Internet access can dial the NCJRS Bulletin Board via modem: dial 301–738–8895. Set modem at 9600 baud, 8–N–1.

Jeremy Travis,

Director, National Institute of Justice.

[FR Doc. 95–19979 Filed 8–11–95; 8:45 am]

BILLING CODE 4410–18–P

National Institute of Justice

[OJP (NIJ) No.1058]

RIN 1121–ZA20

National Institute of Justice ''Solicitation to Develop Guidelines for Death Investigations and for Training of Death Investigators''

AGENCY: U.S. Department of Justice, Office of Justice Programs, National Institute of Justice.

ACTION: Announcement of the availability of the National Institute of Justice's ''Solicitation to Develop Guidelines for Death Investigations and for Training of Death Investigators''.

ADDRESSES: National Institute of Justice, 633 Indiana Avenue, NW., Washington, D.C. 20531.

DATES: The deadline for receipt of proposals is close of business on September 8, 1995.

FOR FURTHER INFORMATION CONTACT: Richard Rau, National Institute of Justice, at (202) 514–6206.

SUPPLEMENTARY INFORMATION: The following supplementary information is provided:

Authority

This action is authorized under the Omnibus Crime Control and Safe Streets Act of 1968, §§ 201–03, as amended, 42 U.S.C. 3721–23 (1988).

Background

Through this solicitation the National Institute of Justice is seeking proposals to develop uniform guidelines for performing medicolegal death investigations, and to develop guidelines for training death investigators. Interested persons should call the National Criminal Justice Reference Service (NCJRS) at 1–800–851–3420 to obtain a copy of ''Solicitation to Develop Guidelines for Death Investigations and for Training of Death Investigators'' (refer to document no. SL000132). The solicitation is available electronically via the NCJRS Bulletin Board, which can be accessed via Internet. Telnet to ncjrsbbs.aspensys.com, or gopher to ncjrs.aspensys.com 71. Those without Internet access can dial the NCJRS Bulletin Board via modem: dial 301–738–8895. Set modem at 9600 baud, 8–N–1.

Jeremy Travis,

Director, National Institute of Justice.

[FR Doc. 95–19980 Filed 8–11–95; 8:45 am]

BILLING CODE 4110–18–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–382]

Entergy Operations, Inc. (Waterford Steam Electric Station, Unit No. 3); Exemption

I

Entergy Operations, Inc., (the licensee) is the holder of Facility Operating License No. NPF–38, which authorizes operation of Waterford Steam Electric Station Unit No. 3 (the facility, Waterford 3). The operating license provides among other things, that it is subject to all rules, regulations, and orders of the Commission now or hereafter in effect. The facility is a pressurized water reactor located at the licensee's site in St. Charles Parish, Louisiana.

II

Section III.D.1.(a) of Appendix J to 10 CFR Part 50 requires the performance of three Type A containment integrated leakage rate tests (ILRTs), at approximately equal intervals during each 10-year service period of the primary containment.

III

By letter dated November 16, 1993, as supplemented by letters dated August 19, 1994, March 30, and June 19, 1995, the licensee requested temporary relief from the requirement to perform a set of three Type A tests at approximately equal intervals during each 10-year service period of the primary containment. The requested exemption would permit a one-time interval extension of the third Type A test by approximately 18 months (from the 1995 refueling outage, currently scheduled to begin in September 1995, to the 1997 refueling outage).

The licensee's request primarily cites the special circumstances of 10 CFR 50.12, paragraph (a)(2)(ii), as the basis for the exemption. They point out that the existing Type B and C testing programs are not being modified by this request and will continue to effectively detect containment leakage caused by the degradation of active containment isolation components as well as containment penetrations. The licensee also indicated that the testing history, structural capability of the containment, and the risk assessment has established that Waterford 3 has a low leakage containment, the structural integrity of the containment is assured, and that there is a neglible risk impact in changing the Type A test schedule. Therefore, application of the regulation in this particular circumstance would not serve, nor is it necessary to achieve, the underlying purpose of the rule.

IV

Section III.D.1.(a) of Appendix J to 10 CFR Part 50 states that a set of three Type A leakage rate tests shall be performed at approximately equal intervals during each 10-year service period.

The licensee proposes an exemption to this section which would provide a one-time interval extension for the Type A test by approximately 18 months. The Commission has determined, for the reasons discussed below, that pursuant to 10 CFR 50.12(a)(1) this exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. The Commission further determines that special circumstances, as provided in 10 CFR 50.12(a)(2)(ii), are present justifying the exemption; namely, that application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule.

The underlying purpose of the requirement to perform Type A containment leak rate tests at intervals during the 10-year service period, is to ensure that any potential leakage pathways through the containment boundary are identified within a time span that prevents significant degradation from continuing or becoming unknown. The NRC staff has reviewed the basis and supporting information provided by the licensee in the exemption request. The NRC staff has noted that the licensee has a good record of ensuring a leak-tight containment. All Type A tests have passed with significant margin and the licensee will continue to perform the existing Type B and C testing to detect containment leakage caused by the degradation of active containment isolation components as well as containment penetrations. The licensee has stated to the NRC Project Manager that they will perform the general containment inspection although it is only required by Appendix J (Section V.A.) to be performed in conjunction with Type A tests. The NRC staff considers that these inspections, though limited in scope, provide an important added level of confidence in the continued integrity of the containment boundary.

The NRC staff has also made use of the information in a draft staff report, NUREG–1493 ''Performance-Based Containment Leak-Test Program,'' which provides the technical justification for the present Appendix J rulemaking effort which also includes a 10-year test interval for Type A tests. The integrated leakage rate test, or Type A test, measures overall containment leakage. However, operating experience with all types of containments used in this country demonstrates that essentially all containment leakage can be detected by local leakage rate tests (Type B and C). According to results given in NUREG–1493, out of 180 ILRT reports covering 110 individual reactors and approximately 770 years of operating history, only 5 ILRT failures were found which local leakage rate testing could not detect. This is 3% of all failures. This study agrees well with previous NRC staff studies which show that Type B and C testing can detect a very large percentage of containment leaks.

The Nuclear Management and Resources Council (NUMARC), now the Nuclear Energy Institute (NEI), collected and provided the NRC staff with summaries of data to assist in the Appendix J rulemaking effort. NUMARC collected results of 144 ILRTs from 33 units; 23 ILRTs exceeded $1.0L_a$. Of these, only nine were not due to Type B or C leakage penalties. The NEI data also added another perspective. The NEI data show that in about one-third of the cases exceeding allowable leakage, the as-found leakage was less than $2L_a$; in one case the leakage was found to be approximately $2L_a$; in one case the as-found leakage was less than $3L_a$; one case approached $10L_a$; and in one case the leakage was found to be approximately $21L_a$. For about half of the failed ILRTs the as-found leakage was not quantified. These data show that, for those ILRTs for which the leakage was quantified, the leakage values are small in comparison to the leakage value at which the risk to the public starts to increase over the value of risk corresponding to L_a (approximately $200L_a$, as discussed in NUREG–1493). Therefore, based on these considerations, it is unlikely that an extension of one cycle for the performance of the Appendix J, Type A test at Waterford 3 would result in significant degradation of the overall containment integrity. As a result, the application of the regulation in these particular circumstances is not necessary to achieve the underlying purpose of the rule.

Based on generic and plant specific data, the NRC staff finds the basis for the licensee's proposed exemption to allow a one-time exemption to permit a schedular extension of one cycle for the performance of the Appendix J, Type A

test to be acceptable provided the general containment inspection (10 CFR Part 50, Appendix J, Section V.A.) is performed.

Pursuant to 10 CFR 51.32, the Commission has determined that granting this Exemption will not have a significant impact on the environment (60 FR 39020).

This Exemption is effective upon issuance and shall expire after March 31, 1997, or at the completion of the 1997 refueling outage whichever comes first.

Dated at Rockville, Maryland, this 3rd day of August 1995.

For the Nuclear Regulatory Commission.

Elinor G. Adensam,

Deputy Director, Division of Reactor Projects III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 95–20027 Filed 8–11–95; 8:45 am]

BILLING CODE 7590–01–P

[Docket No. 50–315]

Indiana Michigan Power Co.; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR–58, issued to Indiana Michigan Power Company (the licensee), for operation of the Donald C. Cook Nuclear Plant, Unit 1, located in Berrien County, Michigan.

The proposed amendment would modify technical specifications 4.4.5.4 and 4.4.5.5, on steam generators, to allow for repair of hybrid expansion joint sleeves under redefined repair boundary limits.

The licensee requested this change on an exigent basis because: (1) The change is associated with steam generator tube repairs during the Unit 1 refueling outage currently in progress, and (2) the empirical data compiled from the Kewaunee Nuclear Plant steam generator tube pulls in March 1995 is the primary support for this amendment and the final implications and conclusions from assessment of that data are just now being formulated. The Unit 1 tube repairs are currently scheduled to begin on August 29, 1995.

The NRC staff has reviewed and concurred with the licensee's reasons for requesting this amendment on an exigent basis.

Before issuance of the proposed 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.

Pursuant to 10 CFR 50.91(a)(6), for amendments to be granted under exigent circumstances the NRC staff must determine that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Operation of the CNP [Donald C. Cook Nuclear Plant] unit 1 in accordance with the proposed license amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Mechanical testing has shown that the inherent structural strength of the HEJ [hybrid expansion joint] provides sufficient integrity such that the tube rupture capability recommendations of RG [Regulatory Guide] 1.121 are met, even for instances of 100% throughwall, 360° circumferentially oriented degradation in the HEJ hardroll lower transition region. Structural integrity recommendations consistent with RG 1.121 are supplied for all tube degradation 1.1 inch or greater below the bottom of the HEJ hardroll upper transition. Based on test data, a bounding SLB [steam line break] leak rate of 0.033 gpm for indications between 1.1 and 1.3 inch below the bottom of the hardroll upper transition is applied. As the leakage data base is expanded and statistical basis established, this SLB leakage allowance may be reduced. For indications existing greater than 1.3 inch below the bottom of the hardroll upper transition, SLB event leakage can be neglected.

Additional prevention from tube rupture is inherently provided by the HEJ geometry. For RCS [reactor coolant system] release rates to exceed the normal makeup capacity of the plant, approximately 120 gpm, the tube must be postulated to experience a complete circumferential separation at the lower transition, and become axially displaced by 3 to 3.25 inches, resulting in complete geometric disassociation between the tube and sleeve resulting in sufficient flow area to support leakage of 120 gpm. During the 1989 plug top release event at North Anna unit 1, primary to secondary release rates were calculated to be less than 80 gpm, for a flow area approximately 4 times larger than the flow area created by a tube which has axially displaced by about 1.25 to 1.5 inch. Analysis of the steam generator indicates that at a 95% cumulative probability, the tube would experience an axial displacement of less than the 1.1 inch boundary. At this level of axial displacement, a ring of metal to metal contact would remain between the tube and sleeve, and leakage would be far less than 120 gpm. Projected leakage at this point is expected to be less than 2.5 gpm. Therefore, implementation of the proposed repair boundary will not result in tube rupture, even for a tube postulated to not behave as predicted by the available test and pulled tube data.

The proposed technical specification change to support the implementation of the HEJ sleeve tube repair boundary for parent tube degradation in the HEJ hardroll lower transition region does not adversely impact any other previously evaluated design basis accident or the results of accident analyses for the current technical specification minimum reactor coolant system flow rate. Plugging limit criteria are established using the guidance of RG 1.121. Furthermore, per RG 1.83 recommendations, the sleeved tube assembly can be monitored through periodic inspections with present eddy current techniques.

(2) The proposed license amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Implementation of the repair boundary will not introduce significant or adverse changes to the plant design basis. Mechanical testing of degraded sleeve joints supports the conclusions of the calculations that the sleeve retains structural (tube burst) capability consistent with RG 1.121. As with [the] initial installation of sleeves, implementation of the alternate criteria cannot interact with other portions of the RCS. Any hypothetical accident as a result of potential tube degradation in the HEJ hardroll lower transition region of the tube is bounded by the existing tube rupture accident analysis. Neither the sleeve design nor implementation of the tube repair boundary defined in Attachment 4 [Westinghouse Electric Corporation Proprietary Report, WCAP–14446] affects any other component or location of the tube outside of the immediate area repaired. In addition, as the installation of sleeves and the impact on current plugging level analyses is accounted for, any postulation that the alternate repair criteria for parent tube degradation in the HEJ hardroll lower transition creates a new or different type of accident is not supported.

(3) The proposed license amendment does not involve a significant reduction in a margin of safety.

The safety factors used in the establishment of the HEJ sleeved tube alternate repair boundary for the disposition of indications in the hardroll lower transition of potentially degraded parent tubes are consistent with the safety factors in the ASME Boiler and Pressure Vessel Code used in steam generator design. Based on the sleeved tube geometry, it is unrealistic to consider that application of the repair boundary could result in single tube leak

rates exceeding the normal makeup capacity during normal operating conditions. The repair boundary established in Attachment 4 has been developed using the methodology of RG 1.121. The performance characteristics of postulated degraded parent tubes of HEJ tube/sleeve joints have been verified by testing to retain structural integrity and preclude significant leakage during normal and postulated accident conditions. Testing indicates that postulated circumferentially separated tubes which the repair boundary addresses would not experience axial displacement during either normal operation or SLB conditions. The existing offsite dose evaluation performed for CNP unit 1 in support of the voltage based plugging criteria for axial ODSCC [outside diameter stress corrosion cracking] at TSP [tube support plate] intersections established a faulted loop primary to secondary leak rate of 12.6 gpm using technical specification dose equivalent Iodine-131 activity levels. Following implementation of the criteria, postulated leakage from all sources must not exceed 12.6 gpm in the faulted loop. Maintenance of this limit will ensure that offsite doses would not exceed the currently accepted limit of 10% of the 10 CFR [Part] 100 guidelines. The repair boundary uses a conservatively established ''per indication'' leak rate for estimation of SLB leakage. This leak rate is applied to all indications left in service as a result of the tube repair boundary, including non-throughwall indications and a limited number of indications of circumferential throughwall extent.

For a postulated indication whose performance is not characteristic of the test and pulled tube data, and which would experience axial displacement at the 95% cumulative probability value following a postulated SLB event with no operator intervention, leakage would not be expected to result in an uncontrolled release of reactor coolant in excess of normal makeup capacity.

For the three pulled tubes and nearly 1,000 crack indications detected in the field, there were no instances of degradation of elevations, (multiple expansion transitions) on either side of the hardroll expansion in the same tube. This includes no instances of non-detected degradation in the upper hydraulic and hardroll upper expansion transitions for the pulled tubes. One tube was identified in the most recent Kewaunee inspection with two separate circumferential crack elevations within the hardroll lower transition. Rapidly occurring degradation would not be expected at the upper transitions, based partly on the field inspection results. The available inspection results include two inspection programs (1994 and 1995) at Kewaunee and one at Point Beach unit 2 (1994). Through these three inspection programs, approximately 11,000 HEJ sleeved tubes have been inspected using advanced probes.

The portions of the installed sleeve assembly which represent the reactor coolant pressure boundary can be monitored for the initiation and progression of sleeve/tube wall degradation, thus satisfying the requirements of Regulatory Guide 1.83.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 15 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 15-day notice period. However, should circumstances change during the notice period, such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 15-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By August 29, 1995, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available 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 Maud Preston Palenske Memorial Library, 500 Market Street, St. Joseph, Michigan 49085. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific

sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If the amendment is issued before the expiration of the 30-day hearing period, the Commission will make a final determination on the issue of no significant hazards consideration. If a hearing is requested, the final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 248–5100 (in Missouri 1-(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to John N. Hannon: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Gerald Charnoff, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street NW., Washington, DC 20037, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated August 4, 1995, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC, and at the local public document room, located at the Maud Preston Palenske Memorial Library, 500 Market Street, St. Joseph, Michigan 49085.

Dated at Rockville, Maryland, this 9th day of August 1995.

For The Nuclear Regulatory Commission.

Tae Kim,

Project Manager, Project Directorate III–1, Division of Reactor Projects—III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 95–20112 Filed 8–11–95; 8:45 am]

BILLING CODE 7590–01–P

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the Office of Management and Budget review of information collection.

SUMMARY: The Nuclear Regulatory Commission (NRC) has recently submitted to the Office of Management and Budget (OMB) for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

1. Type of submission, new, revised, or extension: Revision.

2. The title of the information collection: 10 CFR Parts 60, 72, 73, and 75—Safeguards for Spent Nuclear Fuel of High-Level Radioactive Waste, Proposed Rule.

3. The form number if applicable: Not applicable.

4. How often the collection is required: On occasion.

5. Who will be required or asked to report: As safeguards events occur: Independent spent fuel storage installations, power reactors that have permanently ceased operations, DOE's monitored retrievable storage installations, and DOE's geologic repository operations area.

6. An estimate of the total number of respondents: none required.

7. An estimate of the total number of hours needed to complete the requirement or request: reporting—none; recordkeeping—none; total—none.

8. An indication whether Section 3504(h), Pub. L. 95–511 applies: Applicable.

9. Abstract: The Nuclear Regulatory Commission is proposing to amend its regulations for the safeguards of spent nuclear fuel or high-level radioactive waste. This action is necessary to clarify the safeguards requirements for spent nuclear fuel or high-level radioactive waste stored at independent spent fuel storage installations, power reactors that have permanently ceased operations, monitored retrievable storage installations, and a geological repository operations area.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, DC.

Comments and questions can be directed by mail to the OMB reviewer: Troy Hillier, Office of Information and Regulatory Affairs, (3150–0002,–0127,–0132), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395–3084. The NRC Clearance Officer is Brenda J. Shelton, (301) 415–7233.

Dated at Rockville, Maryland, this 2nd day of August 1995.

For the Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resources Management.

[FR Doc. 95–20028 Filed 8–11–95; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–298]

Nebraska Public Power District; Cooper Nuclear Station; Environmental Assessment and Finding of No Significant Impact

The U. S. Nuclear Regulatory Commission (the Commission) is considering the revocation of an

exemption from the requirements of Appendix R to 10 CFR Part 50 previously issued to the Nebraska Public Power District (NPPD or the licensee) for the Cooper Nuclear Station (CNS), located in Nemaha County, Nebraska.

Environmental Assessment

Identification of the Proposed Action

The proposed action would revoke an exemption from the requirements of Section III.G of Appendix R to 10 CFR Part 50, previously issued to the licensee on September 21, 1983.

The proposed action is in accordance with the licensee's request for withdrawal of the exemption dated December 16, 1994.

The Need for the Proposed Action

The proposed action is needed to eliminate unnecessary commitment by the licensee to upgrade certain fire barriers, which was made in connection with the exemption in question regarding the Critical Switchgear Rooms 1F and 1G on the 932 foot elevation of the reactor building.

Environmental Impacts of the Proposed Action

The Commission has completed its evaluation of the proposed action and concludes that the proposed revocation of exemption is appropriate. The revocation of the exemption would allow the licensee to change a previous commitment to upgrade the fire barriers for the electrical bus duct penetrations in Critical Switchgear Rooms 1F and 1G. This commitment formed part of the basis upon which the staff granted the previous exemption.

The change will not increase the probability or consequences of accidents, no changes are being made in the types of any effluents that may be released offsite, and there is no significant increase in the allowable individual or cumulative occupational radiation exposure. Accordingly, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential nonradiological impacts, the proposed action does involve features located entirely within the restricted area as defined in 10 CFR Part 20. It does not affect nonradiological plant effluents and has no other environmental impact. Accordingly, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the Commission has concluded that there is no measurable environmental impact associated with the proposed action, any alternatives with equal or greater environmental impact need not be evaluated. As an alternative to the proposed action, the staff considered denial of the requested withdrawal of the exemption. Denial of the requested action would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the Final Environmental Statement for the Cooper Nuclear Station, dated February 1973.

Agencies and Persons Consulted

In accordance with its stated policy, on July 21, 1995, the staff consulted with the Nebraska State official, Ms. Julia Schmidt, Division of Radiological Health, Nebraska Department of Health, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

Based upon the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to this action, see the licensee's request for withdrawal of exemption dated December 16, 1994, and the exemption dated September 21, 1983, which are available for public inspection at the Commission's Public Document Room, The Gelman Building, 2120 L Street, NW., Washington, DC, and at the Commission's Local Public Document Room at the Auburn Public Library, 118 15th Street, Auburn, Nebraska 68305.

Dated at Rockville, Maryland, this 7th day of August 1995.

For the Nuclear Regulatory Commission.

James R. Hall,

Senior Project Manager, Project Directorate IV–1, Division of Reactor Projects III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 95–20026 Filed 8–11–95; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice

Pursuant to 49 U.S.C. 44907 D(1), on May 4, 1995, I notified the government of the Philippines that I had determined the Ninoy Aquino International Airport, Manila, Philippines, did not administer and maintain effective security measures. On August 2, 1995, 90 days elapsed since my determination, and I have found that Ninoy Aquino International Airport still does not administer and maintain effective security measures. My determination is based on Federal Aviation Administration assessments which reveal that security measures used at the airport do not meet the standards established by the International Civil Aviation Organization.

Pursuant to 49 U.S.C. 44907 D(1), I have directed that a copy of this notice be published in the **Federal Register,** that my determination be displayed prominently in all U.S. airports regularly being served by scheduled air carrier operations, and that the news media be notified of my determination. In addition, as a result of this determination, all U.S. air carriers and foreign air carriers (and their agents) providing service between the United States and Ninoy Aquino International Airport must provide notice of my determination to any passenger purchasing a ticket for transportation between the United States and Ninoy Aquino International Airport, with such notice to be made by written material included on or with such ticket.

Dated: August 8, 1995.

Federico Peña,

Secretary of Transportation.

[FR Doc. 95–20016 Filed 8–11–95; 8:45 am]

BILLING CODE 4910–62–P

National Highway Traffic Safety Administration

[Docket No. 95–70; Notice 1]

Notice of Receipt of Petition for Decision That Nonconforming 1992, 1993, and 1994 General Motors Suburban Multi-Purpose Passenger Vehicles Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for decision that nonconforming 1992, 1993, and 1994 General Motors Suburban multi-purpose passenger

vehicles (MPVs) manufactured in Mexico are eligible for importation.

SUMMARY: This notice announces receipt by the National Highway Traffic Safety Administration (NHTS) of a petition for a decision that 1992, 1993, and 1994 General Motors Suburban MPVs manufactured in Mexico that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is September 13, 1995.

ADDRESSES: Comments should refer to the docket number and notice number, and be submitted to: Docket Section, Room 5109, National Highway Traffic Safety Administration, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 9:30 am to 4 pm]

FOR FURTHER INFORMATION CONTACT: George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202–366–5306).

SUPPLEMENTARY INFORMATION:

Background

Under 40 U.S.C. 30141(a)(1)(A) (formerly section 108(c)(3)(A)(i)(I) of the National Traffic and Motor Vehicle Safety Act (the Act)), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115 (formerly section 114 of the Act), and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

Wallace Environmental Testing Laboratories, Inc. of Houston, Texas (''Wallace'') (Registered Importer 90–005) has petitioned NHTSA to decide whether 1992, 1993, and 1994 General Motors Suburban MPVs are eligible for importation into the United States. The vehicles that Wallace believes are substantially similar are the 1992, 1993, and 1994 General Motors Suburban MPVs that were manufactured for sale in the United States and certified as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared non-U.S. certified 1992, 1993, and 1994 General Motors Suburban MPVs to their U.S. certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

Wallace submitted information with its petition intended to demonstrate that non-U.S. certified 1992, 1993, and 1994 General Motors Suburban MPVs, as originally manufactured, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 1992, 1993, and 1994 General Motors Suburban MPVs are identical to their U.S. certified counterparts with respect to compliance with Standard Nos. 101 *Controls and Displays,* 102 *Transmission Shift Lever Sequence * * *.,* 103 *Defrosting and Defogging Systems,* 104 *Windshiled Wiping and Washing Systems,* 105 *Hydraulic Brake Systems,* 106 *Brake Hoses,* 107 *Reflecting Surfaces,* 108 *Lamps, Reflective Devices and Associated Equipment,* 109 *New Pneumatic Tires,* 111 *Rearview Mirror,* 113 *Hood Latch Systems,* 114 *Theft Protection,* 115 *Vehicle Identification Number,* 116 *Brake Fluid,* 118 *Power Window Systems,* 124 *Accelerator Control Systems,* 201 *Occupant Protection in Interior Impact,* 202 *Head Restraints,* 203 *Impact Protection for the Driver From the Steering Control System,* 204 *Steering Control Rearward Displacement,* 205 *Glazing Materials,* 206 *Door Locks and Door Retention Components,* 207 *Seating Systems,* 209 *Seat Belt Assemblies,* 210 *Seat Belt Assembly Anchorages,* 211 *Wheel Nuts, Wheel Discs and Hubcaps,* 212 *Windshield Retention,* 214 *Side Impact Protection,* 216 *Roof Crush Resistance,* 219 *Windshield Zone Intrusion,* 301 *Fuel System Integrity,* and 302 *Flammability of Interior Materials.*

Additionally, the petitioner states that non-U.S. certified 1992, 1993, and 1994 General Motors Suburban MPVs comply with the Bumper Standard found in 49 CFR Part 581.

Petitioner also contends that the vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 120 *Tire Selection and Rims for Motor Vehicles other than Passenger Cars:* installation of a tire information placard.

Standards No. 208 *Occupant Crash Protection:* installation of Type 2 lap and shoulder belts at each outboard seating position and a Type 1 lap belt at the center seating position on the rear passenger seat. The petitioner stated that the vehicles are equipped with Type 2 lap and shoulder belts at each outboard seating position on the front and middle passenger seats, and with a Type 1 lap belt in the center seating position on the middle passenger seat.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5109, 400 Seventh Street, S.W., Washington, DC 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8: delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: August 9, 1995.

Marilynne Jacobs,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 95–20022 Filed 8–11–95; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Electronically–Available Information Sources on Economic Sanctions Programs

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department is issuing a list of sources of computer–accessible information for the public's use in keeping informed of and complying with the economic sanctions programs administered by the Office of Foreign Assets Control.

EFFECTIVE DATE: August 8, 1995.

FOR FURTHER INFORMATION CONTACT: Dennis P. Wood, Chief, Compliance Programs Division (tel.: 202/622–2490), Office of Foreign Assets Control, Department of the Treasury, Annex, 1500 Pennsylvania Ave., NW, Washington, DC 20220.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document is itself available as an electronic file on *The Federal Bulletin Board* the day of publication in the **Federal Register** for downloading in WordPerfect 5.1, ASCII, and Postscript formats. The document is also accessible for downloading in ASCII format without charge from Treasury's Electronic Library (''TEL'') in the ''Business, Trade and Labor Mall'' of the FedWorld bulletin board. Select self–extracting file ''T11FR00.EXE'' in TEL. The means of access to these information services are described in this notice.

Background

This notice describes various public and private information sources accessible by computer that provide information concerning the economic sanctions programs administered by the Office of Foreign Assets Control (''OFAC''). Information available for reading or downloading includes notices of blockings, statutory and Executive order authorities, regulations, regulatory amendments, and lists of blocked entities, specially designated nationals, and specially designated terrorists. OFAC encourages the public to utilize these sources to remain current with developments in economic sanctions programs for informational and compliance purposes.

OFAC PUBLIC INFORMATION ACCESSIBLE BY COMPUTER

Sources Available to the General Public:

U.S. Treasury Department's Electronic Library (''TEL''):

The Treasury Department maintains a free electronic library called ''TEL'' on the FedWorld bulletin board, a service of the National Technical Information Service. TEL can be reached 24 hours a day, 7 days a week, using standard communications software and a modem, either directly, by dialing 703/321–3339, or over the Internet using one of the following protocols: Telnet = fedworld.gov (192.239.93.3); FTP Site = ftp.fedworld.gov (192.239.92.205); World Wide Web (Home Page) = http://www.fedworld.gov. Once access to FedWorld has been gained, select option ''[C],'' the ''Business, Trade, and Labor Mall;'' then ''[E],'' ''Treasury's Electronic Library.'' OFAC files are available for downloading in camera–ready ''*.PDF'' format as well as in a self–extracting ASCII ''*.EXE'' format. Each bears the prefix ''T11.'' OFAC's camera–ready brochure on Cuba, for example, is called ''T11CUBA.PDF.'' OFAC's self–extracting ASCII file containing all of OFAC's brochures as well as the latest listing of *Specially Designated Nationals and Blocked Persons* (the ''SDN list'') in DOS–format is called ''T11FAC00.EXE.'' A major advantage of TEL, besides Internet access, is that there is no charge to any user to download files. Adobe Acrobat Readers™ are available free to view and print the ''*.PDF'' files. Those needing a free Acrobat Reader™ may download the file from the Internal Revenue Service ''utilities'' library by typing the command ''/go IRISGR'' at FedWorld's main prompt. FedWorld's help desk number is 703/487–4608; the business office number is 703/487–4648.

U.S. Commerce Department's Economic Bulletin Board (''EBB'')

The U.S. Department of Commerce operates an electronic bulletin board called the ''EBB.'' The EBB can be reached 24 hours a day, 7 days a week, using standard communications software and a modem, either directly, by dialing 202/482–3870 (for 2400 bps connections) or 202/482–2584 or 202/482–2167 (for 9600 bps connections), or over the Internet using the Telnet protocol: Telnet = ebb.stat–usa.gov. A free, limited–access service is available to those who are unfamiliar with the Commerce Board. Otherwise, access is by subscription at a nominal charge. The EBB is used extensively by U.S. exporters seeking information on trade leads. All OFAC publications in ASCII format, including the very latest version of the alphabetized SDN listings, are available for downloading from ''File Area #17'' on the Board. Commerce Department Export Denial Order information is also available in the same general file area. OFAC sheets can be individually downloaded by the public or all OFAC informational material can be transferred as a compressed self–extracting DOS archive file called ''FACDATA.EXE.'' Once an individual accesses the Board, all that needs to be done to locate OFAC material is to choose ''F'' from the main menu to access a FILES subsystem, then choose ''L'' for LIST, and type ''17'' for OFAC. The EBB's Help Line is 202/482–1986 (Monday to Friday, 8:30 a.m. through 4:30 p.m. Eastern Time).

U.S. Commerce's National Trade Data Bank (''NTDB'')

The U.S. Department of Commerce operates a CD–Rom service providing a massive amount of international trade information on a monthly basis to small and medium sized companies. There is a nominal charge for a subscription. The CD–Rom service is also available free of charge at Commerce offices nationwide as well as nearly 1,000 Federal depository libraries. OFAC data is in ASCII format and fully searchable. For information, call 202/482–1986.

U.S. Commerce's STAT–USA/FAX

The U.S. Department of Commerce operates an automated fax–on–demand service that includes OFAC data. Users can call 202/482–0005 from a fax machine's handset 24 hours a day, 7 days a week. For a nominal subscription charge, subscribers are entitled to 6 files per day without size restrictions. OFAC is posting in print (''camera ready'') copy the latest listing of *Specially Designated Nationals and Blocked Persons*, cumulative *Changes to the Listing of Specially Designated Nationals and Blocked Persons*; and OFAC's brochure entitled *Foreign Assets Control Regulations for Exporters and Importers*.

World Wide Web (''WWW'')

All of OFAC's program brochures, as well as SDN list information, is available in downloadable camera–ready Adobe Acrobat™ ''*.PDF'' format to subscribers to the U.S. Commerce Department's World Wide Web Server (STAT–USA/Internet) with access at //www.stat–use.gov. For information call 202/482–1986.

OFAC is in the final stages of developing a new service to provide direct Internet access to OFAC's information over a Treasury World Wide Web Server and plans to coordinate update notices with a

Federal Web Locator. Details will be published as soon as available.

U.S. Government Printing Office's *The Federal Bulletin Board*

The U.S. Government Printing Office (''GPO'') operates *The Federal Bulletin Board*, which can be accessed 24 hours a day, 7 days a week, by direct dialing 202/512–1387 from a modem using any communications software. Type ''/GO FAC.'' The system detects modem speed. Access over the Internet is available using the Telnet protocol: Telnet = federal.bbs.gpo.gov 3001. (The ''[space] 3001'' is important as it specifies the proper ''entry'' port for Telnet.) User assistance is available from 7:00 a.m. to 5:00 p.m. Eastern Time, Monday through Friday by calling 202/512–1530. OFAC's information is located in a series of file libraries for downloading in ASCII, WordPerfect, and ''*.PDF'' or ''Postscript'' formats, and includes, in addition to OFAC brochures and SDN lists, the full text of OFAC sanctions regulations as published in chapter V of Title 31, Code of Federal Regulations, statutory and Executive order authority for OFAC sanctions, and every **Federal Register** notice, rule, or policy statement OFAC publishes. **Federal Register** notices are posted electronically to the Board at the same time they are printed in the **Federal Register**. The file libraries from which users may download information are: ''FAC31CFR'' (containing the most recent annual text of chapter V, Title 31, CFR), ''FAC—31FR'' (containing OFAC's **Federal Register** documents), ''FAC—BRO'' (containing all of OFAC's brochures as well as a comprehensive self–extracting ''*.EXE'' file of brochures and SDN lists in DOS format), ''FAC—MISC'' (containing press releases and special items, such as the Libyan bank chart), and ''FAC—SDN'' (containing the very latest releases of the master SDN lists as well as a comprehensive self–extracting ''*.EXE'' file of all brochures and SDN lists in DOS format). User pricing for The Federal Bulletin Board is based on the size of files downloaded. Contact the GPO for information: 202/512–1530.

U.S. Maritime Administration's Marlinespike Bulletin Board System

The U.S. Maritime Administration operates a free electronic bulletin board called ''Marlinespike'' which can be accessed via modem at 202/366–8505, with voice help at 202/366–9991. OFAC's brochures and SDN information can be scanned on–line or downloaded for further use.

U.S. Customs Service's Customs Electronic Bulletin Board

The U.S. Customs Service maintains a free Customs Electronic Bulletin Board geared especially toward customs house brokers. OFAC's information is available as a date–specific self–extracting DOS file (''OFAC*.EXE'' in File Area #15, ''Customs Extra!''). Modem access is at 703/440–6155, with voice system support at 703/440–6236.

Sources Available to Banks:

U.S. Council on International Banking (''USCIB''—headquartered in New York)

The U.S. Council on International Banking is a nationwide banking industry interest group concentrating on the international banking operations area. Member banks have free access to the USCIB's electronic bulletin board, *INTERCOM*. All OFAC publications, including the latest alphabetized SDN listings, are available to be downloaded from the ''MAIN Conference'' on *INTERCOM*. OFAC files can be individually downloaded by banks in camera–ready ''*.PDF'' format, or all of them can be transferred as a compressed self–extracting ASCII archive file called ''OFAC*.EXE.'' In addition, OFAC announces via system bulletins all major sanctions actions as they occur.

International Banking Operations Association (''IBOA''—headquartered in Miami)

The International Banking Operations Association is a membership organization of banks in the southern United States. IBOA has a ''Wildcat'' bulletin board which includes, in its Regulatory Conference, a compressed self–extracting ASCII archive file called ''OFAC*.EXE'' containing all OFAC publications, as well as the latest SDN listings. Individual brochures may also be downloaded by users as camera–ready copy in ''*.PDF'' format. System bulletins are posted on IBOA's board covering major sanctions actions as they occur.

Clearing House Interbank Payments System (New York Clearing House Association)

The Clearing House Interbank Payments System ''CHIPS'' maintains a special bulletin board specifically to receive and sort OFAC SDN information. Bankers should contact the The New York Clearing House Association for information. In addition, system bulletins are electronically transmitted to CHIPS regarding all major sanctions actions for immediate broadcast to members.

Office of the Comptroller of the Currency's *OCC Information Line*

The Office of the Comptroller of the Currency operates a special 24–hour–a–day fax–on–demand service for National banks and examiners. The computer–based system provides copies of documents from any touchtone phone by calling 202/479–0141 and following voice prompts. OCC's Communications Division may be reached at 202/874–4960. Documents regularly updated on the system include OFAC's listing of *Specially Designated Nationals and Blocked Persons* split alphabetically into two files, A–K and L–Z; cumulative *Changes to the Listing of Specially Designated Nationals and Blocked Persons*, and OFAC's *Foreign Assets Control Regulations for the Financial Community*.

Bank Regulatory Agencies

OFAC provides official electronic notice regarding major sanctions actions to some 5000 on–line Fedwire depository institutions through the Federal Reserve Bank of New York. The message from the New York Fed is retransmitted through each Federal Reserve District. Such messages are limited to 14 lines of 80 characters. (OFAC also distributes from time to time printed copies of important sanctions information to depository institutions throughout the United States through each of the Federal bank regulatory agencies.)

Dated: July 27, 1995.

R. Richard Newcomb,

Director, Office of Foreign Assets Control.

Approved: August 2, 1995.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 95–19949 Filed 8–8–95; 3:19 pm]

BILLING CODE 4810–25–F

DEPARTMENT OF VETERANS AFFAIRS

Special Medical Advisory Group; Notice of meeting

The Department of Veterans Affairs gives notice that a meeting of the Special Medical Advisory Group, authorized by Title 38, U.S.C., Section 7312, will be held at the Department of Veterans Affairs, Room 230, 810 Vermont Avenue, N.W., Washington, D.C., on August 31, 1995.

The meeting will convene at 8:30 a.m. (EST) and adjourn at approximately 4:00 p.m. (EST). The meeting will be open to the public up to the seating capacity of the room. Those wishing to attend should contact Susan Hall, Office of the Deputy Under Secretary for health, at 202–273–5813, no later than August 25.

The committee objective is to advise the Secretary of Veterans Affairs, through the Under Secretary for Health,

relative to the care and treatment of disabled veterans and other matters pertinent to the Veterans Health Administration.

The following is the intended agenda for the meeting:

Agenda

8:30
Call to order and introductions
Minutes from 5/10/95 meeting Status of recommendations
8:45–9:10
Update–Vision for Change
9:10–12:00
Discussion:
Restructuring of VHA/Academic Affiliations
12:00–1:15
Lunch
1:15–3:45
Discussion:
Research Options for Restructuring
3:45–4:00
Closing summary and remarks
4:00
Adjourn

Dated: August 1, 1995.

By Direction of the Secretary.

Heyward Bannister,

Committee Management Officer.

[FR Doc. 95–19943 Filed 8–11–95; 8:45 am]

BILLING CODE 8320–01–M

Sunshine Act Meetings

Federal Register

Vol. 60, No. 156

Monday, August 14, 1995

This section of the FEDERAL REGISTER contains notices of meetings published under the ''Government in the Sunshine Act'' (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FARM CREDIT ADMINISTRATION

Farm Credit Administration Board; Regular Meeting

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act (5 U.S.C. 552b(e)(3)), that the September 14, 1995 regular meeting of the Farm Credit Administration Board (Board) will not be held and that a special meeting of the Board is scheduled for Tuesday, September 12, 1995 at 2:15 p.m. An agenda for this meeting will be published at a later date.

FOR FURTHER INFORMATION CONTACT: Floyd Fithian, Secretary to the Farm Credit Administration Board, (703) 883–4025, TDD (703) 883–4444.

ADDRESS: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090.

Dated: August 9, 1995.

Floyd Fithian,

Secretary, Farm Credit Administration Board.

[FR Doc. 95–20162 Filed 8–10–95; 3:04 pm]

BILLING CODE 6705–01–P–M

federal register

Monday
August 14, 1995

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Part 411

Medicare Program; Physician Financial Relationships With, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services; Financial Relationship Reporting Requirements: Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 411

[BPD–674–FC]

RIN: 0938–AF40

Medicare Program; Physician Financial Relationships With, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period provides that, if a physician or a member of a physician's immediate family has a financial relationship with an entity, the physician may not make referrals to the entity for the furnishing of clinical laboratory services under the Medicare program, except under specified circumstances. It contains revisions to our proposal of March 11, 1992, based on comments submitted by the public. Further, it incorporates the new expansions and exceptions created by the Omnibus Budget Reconciliation Act of 1993 and the amendments in the Social Security Act Amendments of 1994 (SSA '94), that are related to referrals for clinical laboratory services and have a retroactive effective date of January 1, 1992.

In addition, we are responding to comments received on the interim final rule with comment period (published on December 3, 1991) that set forth Medicare reporting requirements for the submission by certain health care entities of information about their relationships with physicians. That document implemented the reporting requirements of section 1877(f) of the Social Security Act. This rule revises those requirements to incorporate the amendments to section 1877(f) made by SSA '94, to apply to any further reporting we may require.

EFFECTIVE DATES: The regulations are effective September 13, 1995.

Comment Date: Comments on the new provisions added by the Omnibus Budget Reconciliation Act of 1993 and any changes in section 1877 that resulted from the Social Security Act Amendments of 1994 will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 13, 1995.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–674–FC, P.O. Box 26688, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C–5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–674–FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

For comments that relate to information collection requirements, mail a copy of the comments to: Allison Herron Eydt, HCFA Desk Officer, Office of Information and Regulatory Affairs, Room 3001, New Executive Office Building, Washington, DC 20503.

Copies: To order copies of the **Federal Register** containing this document, send your request to the Government Printing Office, ATTN: New Orders, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing your Visa or Master Card number and expiration date to (202) 512–2250. The cost for each copy is $8.00. As an alternative, you may view and photocopy the **Federal Register** document at most libraries designated as U.S. Government Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Betty Burrier, (410) 786–0191.

SUPPLEMENTARY INFORMATION: To assist readers in referencing sections contained in this final rule, we are providing the following table of contents:

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I. Legislation and Regulations—Chronological Background

In section 6204 of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Public Law 101–239, enacted on December 19, 1989), the Congress added a provision to the Social Security Act (the Act) that governs whether physicians who have financial relationships (or who have immediate family members with financial relationships) with a health care entity can refer Medicare patients to that entity for clinical laboratory services. This provision was amended by section 4207(e) of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Public Law 101–508, enacted on November 5, 1990); section 13562 of the Omnibus Budget Reconciliation Act of 1993 (OBRA '93) (Public Law 103–66, enacted on August 10, 1993); and section 152 of the Social Security Act Amendments of 1994 (SSA '94) (Public Law 103–432, enacted on October 31, 1994). As discussed below, we published an interim final rule in 1991 concerning financial relationship reporting requirements, and we published a proposed rule in 1992 concerning physician referrals to clinical laboratories.

A. OBRA '89

Section 6204 of OBRA '89 added section 1877, ''Limitation on Certain Physician Referrals,'' to the Act. (Unless otherwise indicated, all references below to various sections of the law are references to the Act.) In general, section 1877 as added by OBRA '89 prohibits a physician with a financial relationship with an entity that furnishes clinical laboratory services (or a physician with an immediate family member who has such a relationship) from making a referral to that entity for clinical laboratory services for which Medicare would pay. It also prohibits the entity from billing Medicare, an individual, a third-party payor, or other entity for an item or service furnished as a result of a prohibited referral. Additionally, it requires a refund of any amount collected from an individual as the result of a billing for an item or service furnished under a prohibited referral. The statute provides for certain exceptions to the prohibition.

B. OBRA '90

Section 4207(e) of OBRA '90 amended certain provisions of section 1877 to clarify definitions and reporting requirements relating to physician ownership and referral and to provide an additional exception to the prohibition.

C. Federal Register Documents

On December 3, 1991, we published an interim final rule in the **Federal Register**, at 56 FR 61374, that set forth reporting requirements under the Medicare program for health care entities furnishing clinical laboratory services (and certain other services as discussed below) to submit information about their relationships with physicians. On March 11, 1992, we published a proposed rule in the **Federal Register**, at 57 FR 8588, that proposed regulations concerning the provisions of section 1877, as amended by OBRA' 90, concerning physician referrals to clinical laboratories. Although we summarize the provisions of the interim final rule and proposed rule in section II of this document, readers may want to refer to the interim final rule and proposed rule for additional information on the statutory provisions as amended by OBRA '90 and for the specifics of our proposals.

D. OBRA '93 and SSA '94

Section 13562 of OBRA '93 included extensive revisions to section 1877. Some of the revisions simply elaborate on or amend existing law, while others institute entirely new provisions. With regard to referrals for clinical laboratory services, some of the provisions of OBRA '93 have a prospective effective date of January 1, 1995, while others have a retrospective effective date of January 1, 1992. Most dramatically, section 13562 extends section 1877 to cover 10 additional designated health services, beginning with referrals made after December 31, 1994.

In addition, section 13624 added paragraph (r) to section 1903. This section extends certain provisions of section 1877 to the Medicaid program effective on or after December 31, 1994. That is, this section prohibits Medicaid payments to a State for designated health services furnished on the basis of a referral that would result in the denial of payment under Medicare if Medicare provided for coverage of the service to the same extent and under the same terms and conditions as under the State plan. This section also provides that the reporting requirements under 1877(f) and the civil money penalty provisions for failure to report information under section 1877(g)(5) apply to entities that furnish services covered under the Medicaid program in the same manner as they apply to entities that furnish Medicare covered services.

SSA '94 amended the reporting requirements that entities providing Medicare (and now Medicaid) items and services have to meet for purposes of the referral prohibition, changed some of the designated health services, and altered the effective date provisions in OBRA '93. The changes in the effective date provisions have altered the dates on which some of the provisions relating to referrals for clinical laboratory services go into effect prior to January 1, 1995. These changes have been reflected in this final rule.

A separate notice of proposed rulemaking will be published to address those provisions of OBRA '93 that relate to designated health services (including clinical laboratory services) and that become effective January 1, 1995. In other words, the discussion in this

preamble and the regulations established as a result of the publication of this final rule with comment period are in the context of referrals for clinical laboratory services and address only those provisions of section 1877 that are effective as of January 1, 1992.

Even though we will cover the designated health services under a separate proposed rule, this final rule with comment will affect how we review referrals involving any of the designated health services. The statute groups clinical laboratory services together with all other designated health services beginning on January 1, 1995. Generally, the prohibition in the statute and the exceptions are drafted so that they apply equally to situations involving referrals for any of the designated health services, including referrals for clinical laboratory services. As a result, we believe that a majority of our interpretations in this final rule with comment will apply to the other designated health services.

Until we publish a rule covering the designated health services, we intend to rely on our language and interpretations in this final rule when reviewing referrals for the designated health services in appropriate cases. We believe appropriate cases are those in which our interpretations of the statute clearly apply equally to referrals for clinical laboratory services and other designated health services. For example, we have defined the term ''immediate family member'' for purposes of this final rule with comment. We will be guided by this definition when we review referrals for the designated health services.

The following discussion covers the basic prohibition in section 1877 and fundamental concepts and definitions, while it highlights the changes to section 1877 made by OBRA '93, as amended by SSA '94, that relate to clinical laboratory services and that became effective on January 1, 1992.

1. General Prohibition

The prohibition of certain referrals is contained at section 1877(a)(1) of the Act. The provisions of that section remained unchanged by OBRA '93 until January 1, 1995. With certain exceptions, section 1877(a)(1)(A) prohibits a physician from making a referral to an entity for the furnishing of clinical laboratory services, for which Medicare would otherwise pay, if the physician (or a member of the physician's immediate family) has a financial relationship with that entity. (''Financial relationship,'' as described by the Act, is discussed under I.D.4, below.) Further, section 1877(a)(1)(B) prohibits an entity from presenting or causing to be presented a Medicare claim or bill to any individual, third party payor, or other entity for clinical laboratory services furnished under a prohibited referral.

2. Definition of Referral

The definition of ''referral,'' as it relates to clinical laboratory services, was not changed by OBRA '93. Section 1877(h)(5) specifies that the following requests constitute a referral:

- For physicians' services, the request by a physician for an item or service for which payment may be made under Medicare Part B, including the request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician).
- For other items, the request or establishment of a plan of care by a physician that includes the furnishing of clinical laboratory services.

Under section 1877(h)(5)(C), however, a referral does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services if the services are furnished by (or under the supervision of) the pathologist as a result of a consultation requested by another physician.

3. Definitions of Compensation Arrangement and Remuneration

The predecessor provision of section 1877(h)(1) (that is, section 1877(h)(1) as it read before the enactment of OBRA '93) defines a ''compensation arrangement'' as any arrangement involving any remuneration between a physician (or an immediate family member) and an entity. It defines ''remuneration'' to include any remuneration, directly or indirectly, overtly or covertly, in cash or in kind. OBRA '93 amends section 1877(h)(1) by adding paragraph (h)(1)(C) to enumerate certain exceptions to the above definition of compensation arrangement. Paragraph (h)(1)(C) specifies that a compensation arrangement does not include the following types of remuneration:

- The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.
- The provision of items, devices, or supplies that are used solely to—
  + Collect, transport, process, or store specimens for the entity providing the item, device, or supply; or
  + Order or communicate the results of tests or procedures for the entity.
- A payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—
  + The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the plan and the physician;
  + The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual;
  + The amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals; and
  + The payment meets other requirements the Secretary may impose by regulation as needed to protect against Medicare program or patient abuse.

4. Financial Relationships

Under OBRA '93, section 1877(a)(2) continues to describe a financial relationship between a physician (or an immediate family member of a physician) and an entity as being an ownership or investment interest in the entity or a compensation arrangement between a physician (or immediate family member) and the entity. The statute also continues to provide that an ownership or investment interest may be established through equity, debt, or other means. (Note that effective for referrals made on or after January 1, 1995, OBRA '93 provides that an ownership or investment interest also includes an interest in an entity that holds an ownership or investment interest in any entity furnishing the clinical laboratory service or other designated health services.)

5. General Exceptions to the Prohibition on Physician Referrals

Section 1877(b) provides for general exceptions to the prohibition on referrals. (General exceptions are exceptions that apply to both ownership/investment and compensation.) Because these exceptions frequently refer to a ''group practice,'' we begin our discussion of the exceptions by describing ''group practice'' as defined by the statute at section 1877(h)(4).

Until January 1, 1995, OBRA '93 continued to define ''group practice'' as a group of two or more physicians legally organized as a partnership,

professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association, that meets the following conditions:

- Each physician member of the group furnishes substantially the full range of services that the physician routinely furnishes, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel.
- Substantially all of the services of the physician members of the group are furnished through the group, are billed in the name of the group, and amounts so received are treated as receipts of the group.
- The overhead expenses of and the income from the practice are distributed in accordance with methods previously determined. (OBRA '93 eliminates the requirement that the methods be previously determined by members of the group.)
- The group practice complies with all other standards established by the Secretary in regulations.

In addition, OBRA '93 amended section 1877(h)(4). The predecessor provision of section 1877(h)(4) provided that, in the case of a faculty practice plan associated with a hospital with an approved medical residency training program in which physician members may furnish a variety of different specialty services and furnish professional services both within and outside the group, as well as perform other tasks such as research, the conditions contained in the definition of ''group practice'' apply only with respect to the services furnished within the faculty practice plan. OBRA '93 added, as an addition to a faculty practice plan associated with a hospital, a faculty practice plan associated with an institution of higher education or a medical school.

(Note that OBRA '93 makes other changes to the definition of group practice that will become effective January 1, 1995.)

a. Exception—Physicians' Services

Section 1877(b)(1) continues to specify that the prohibition does not apply to services furnished on a referral basis if the services are physicians' services, as defined in section 1861(q), furnished personally by (or under the personal supervision of) another physician in the same group practice (as defined in section 1877(h)(4)) as the referring physician.

b. Exception—In-Office Ancillary Services

Section 1877(b)(2) continues to specify that the prohibition does not apply to referrals for certain in-office ancillary services. Both the predecessor provisions and current provisions of section 1877(b)(2) contain requirements that must be met in order for the exception to apply. These requirements concern who may furnish the services, where the services are furnished, and how the services must be billed.

Who May Furnish the Services

Under the predecessor provisions of section 1877(b)(2)(A)(i), the services had to be personally furnished by the referring physician, a physician who was a member of the same group as the referring physician, or individuals employed by the physician or group practice and who were personally supervised by the physician or by another physician in the group practice. OBRA '93 amends this provision to require that the individual performing the service be *directly* supervised by the physician or by another physician in the group practice and dropped the employment requirement.

Where the Services May Be Furnished

The predecessor provision of section 1877(b)(2)(A)(ii) required that the services be furnished in either of the following:

- A building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of clinical laboratory services.
- In the case of a referring physician who is a member of a group practice, in another building that is used by the group practice for the centralized provision of the group's clinical laboratory services.

OBRA '93 amended this provision to require, in the group practice situation, that the building be used for the provision of some or all of the group's clinical laboratory services. That is, this provision no longer requires that the provision of laboratory services be centralized at that site.

The statute contains an undesignated paragraph at the end of the group practice location requirements that reads as follows: ''unless the Secretary determines other terms and conditions under which the provision of such services does not present a risk of program or patient abuse, * * *''

We believe that, because of the way the paragraph is indented, how it applies to the in-office ancillary services exception is ambiguous. It could apply to all of paragraph (b)(2)(A)(ii) or apply to only paragraph (b)(2)(A)(ii)(II). If it applies to all of paragraph (b)(2)(A)(ii), it would affect both solo and group practitioners. If it applies to only paragraph (b)(2)(A)(ii)(II), it would affect only group practices.

The Conference Report that accompanied OBRA '93 (H. Rep. No. 213, 103rd Cong., 1st Sess. 810 (1993)) points out that the conference agreement includes an exception for clinical laboratory services provided by a group practice that has multiple office locations. The Report also says that the conferees expect that the Secretary will publish regulations specifying other terms and conditions under which group practices may qualify for a group practice exception to the general prohibition. Arguably, the Congress had only group practices in mind in drafting the provision at issue. Therefore, we believe that the undesignated paragraph applies to only paragraph (b)(2)(A)(ii)(II), which concerns the site requirements as they relate to a group practice.

In addition, this paragraph could be read to mean that the Secretary is allowed to *liberalize* the circumstances in paragraph (b)(2)(A)(ii)(II) (the building/location requirements) if she determines that there are other, additional ''terms and conditions'' under which an entity can provide services without presenting a risk of program or patient abuse. In this case, the interpretation would not appear redundant with the undesignated paragraph that follows at the end of section 1877(b)(2)(B), which authorizes the Secretary to impose additional ''requirements'' for application of the in-office exception.

We could also interpret ''other terms and conditions'' as including any different terms or conditions, whether they are more restrictive or more liberal, that the Secretary may add to the list in paragraph (b)(2)(A)(ii) or in (b)(2)(A)(ii)(II). However, more restrictive conditions could make the two undesignated paragraphs redundant.

Alternatively, the paragraph following section 1877(b)(2)(A)(ii)(II)(bb) could be read to mean that the circumstances in (b)(2)(A)(ii) must be met for the exception to apply unless the Secretary determines *other* terms and conditions under which there will be no patient or program abuse, and which should be substituted for the list of conditions in (b)(2)(A)(ii). We do not believe that this reading would conflict with the paragraph that follows section 1877(b)(2)(B), because the Secretary could then still add more requirements to the list of those in paragraph (b)(2)(A)(ii) (with (b)(2)(A)(ii) now consisting of the Secretary's substitutions). Therefore, it is our

interpretation that this paragraph is intended to provide for the possibility of a liberalization of the conditions as described in section 1877(b)(2)(A)(ii)(II). At this time, we are not imposing any additional terms or conditions for the application of this provision, and we solicit comments on this issue.

Billing

Section 1877(b)(2)(B) continues to require that the ancillary services be billed by one of the following:

- The physician performing or supervising the services.
- A group practice of which the performing or supervising physician is a member.
- An entity that is wholly owned by the physician or group practice.

(Note that, effective January 1, 1995, the statutory definition of group practice requires that a group practice bill under a billing number assigned to the group.)

c. Exception—Certain Prepaid Health Plans

Section 1877(b)(3) continues to specify that the prohibition on referrals does not apply to services furnished to their enrollees by Medicare-contracting health maintenance organizations (HMOs), Medicare-contracting competitive medical plans (CMPs), and prepaid health care organizations under a contract or agreement with us. OBRA '93 expands the exception to apply it to services furnished to their enrollees by Federally-qualified HMOs. (The Federally-qualified HMOs are not required to have a contract or agreement with us in order for the exception to apply.)

d. Exception—Hospital Financial Relationship Unrelated to the Provision of Clinical Laboratory Services

Before the enactment of OBRA '93, section 1877(b)(4) provided a general exception to the prohibition in the case of a financial relationship with a hospital if the financial relationship did not relate to the provision of clinical laboratory services. OBRA '93 omitted this general exception, replacing it with section 1877(e)(4). Section 1877(e)(4) provides that remuneration from a hospital to a physician that is unrelated to the provision of clinical laboratory services does not constitute compensation that would trigger the prohibition on referrals. However, SSA '94 revised the effective date provision in section 13562(b)(2)(B) of OBRA '93. This effective date provision now states that section 1877(b)(4) continues to apply until January 1, 1995 as it was in effect before OBRA '93.

e. Other Exceptions

Section 1877(b) (currently at (b)(4)) continues to authorize the Secretary to provide in regulations for additional exceptions for financial relationships, beyond those specified in the statute, if she determines they do not pose a risk of Medicare program or patient abuse.

6. Exceptions Applicable Only to Financial Relationships Consisting of Ownership or Investment Interests

OBRA '93 continues to provide that certain ownership or investment interests do not constitute a ''financial relationship'' for purposes of the section 1877 prohibition on referrals.

a. Exception—Certain Investment Securities and Shares

Before OBRA '93, section 1877(c) contained an exception for ownership of investment securities, provided they were purchased on terms generally available to the public and were in a corporation that was (1) listed for trading on various specified stock exchanges and (2) had, at the end of the corporation's most recent fiscal year, total assets exceeding $100 million. These provisions were reflected in the proposed rule.

OBRA '93 has modified this provision in several ways. First, investment securities no longer have to be those purchased on terms generally available to the public; they must only be those which ''may be purchased'' on terms generally available to the public. Second, the securities can be those listed on additional exchanges, including any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis.

Third, the investment securities no longer have to be in a corporation with $100 million in total assets at the end of a fiscal year; now the holdings of the corporation must be measured in terms of ''stockholder equity,'' and the amount has been modified from $100 million to $75 million. This amount can now either be measured at the end of the most recent fiscal year or based on the corporation's average during the previous 3 fiscal years.

Finally, OBRA '93 extends the exception to apply to mutual funds, exempting ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75 million.

Under the effective date provisions of OBRA '93, the amended version of section 1877(c) was not effective until January 1, 1995. SSA '94 revised the effective date provision to make the amended version of section 1877(c) effective retroactively to January 1, 1992; however, the revised effective date provision states that, prior to January 1, 1995, the amended section 1877(c) does not apply to any securities of a corporation that meets the requirements of section 1877(c)(2) as they appeared prior to OBRA '93. Section 1877(c)(2), prior to OBRA '93, contained the requirement that a corporation have $100 million in total assets. This final rule reflects the amended version of section 1877(c). It also specifies that, until January 1, 1995, ownership of investment securities in a corporation with $100 million in total assets can also qualify for the exception.

b. Exception—Ownership or Investment Interest in Certain Health Care Facilities

Section 1877(d) continues to provide additional exceptions to the prohibition on physician referrals for an ownership or investment interest of a physician (or an immediate family member of the physician) in three types of facilities:

- A hospital located in Puerto Rico.
- A laboratory located in a rural area (that is, an area outside of a Metropolitan Statistical Area as defined in section 1886(d)(2)(D)).
- A hospital outside of Puerto Rico if the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

(Note that OBRA '93 contains changes to the above provisions that became effective on January 1, 1995. These extend the exceptions to designated health services and modify the exception for rural providers. Before OBRA '93, the exception applied if the laboratory furnishing the services is in a rural area (as defined in section 1886(d)(2)(D). The statute now provides that the exception applies in the case of designated health services furnished in a rural area (as defined in section 1886(d)(2)(D)) by an entity, if substantially all of the designated health services furnished by the entity are furnished to individuals residing in the rural area.

7. Exceptions Applicable Only to Financial Relationships Consisting of Certain Compensation Arrangements

Section 1877(e) continues to provide that certain compensation arrangements are not considered a ''financial

relationship'' for purposes of the prohibition on physician referrals.

a. Exception—Rental of Office Space

OBRA '93 amends the exception in section 1877(e)(1) for payments made by a lessee to a lessor for the use of office space, but delayed the effective date of the amendments until January 1, 1995. Section 152(c) of SSA '94 amends the effective date provision for OBRA '93 to eliminate this delay. The amended version of this exception now contains a requirement that the rented space not exceed that which is reasonable and necessary for the legitimate business purposes of the lease and that the space be used exclusively by the lessee during the lease. In addition, the exception now allows a lessee to pay for common areas shared with other occupants. Specifically, this provision states that payments made by a lessee to a lessor for the use of a premises do not constitute a compensation arrangement that would trigger the prohibition on referrals if the following conditions are met:

- The lease is set out in writing, signed by the parties, and specifies the premises covered by the lease.
- The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if these payments do not exceed the lessee's pro rata share of expenses for that space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.
- The lease provides for a term of rental or lease for at least 1 year.
- The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.
- The lease would be commercially reasonable even if no referrals were made between the parties.
- The lease meets any other requirements the Secretary may impose by regulation as needed to protect against program or patient abuse.

b. Exception—Rental of Equipment

OBRA '93 added a new provision, section 1877(e)(1)(B), effective January 1992, that excepts from the definition of compensation arrangements payments made by a lessee of equipment to the lessor of the equipment for the use of the equipment if the following conditions are met:

- The lease is set out in writing, signed by the parties, and specifies the equipment covered by the lease.
- The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the rental or lease and is used exclusively by the lessee when being used by the lessee.
- The lease provides for a term of rental or lease of at least 1 year.
- The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- The lease would be commercially reasonable even if no referrals were made between the parties.
- The lease meets any other requirements the Secretary may impose by regulation as needed to protect against Medicare program or patient abuse.

c. Exception—Bona Fide Employment Relationship

The predecessor provision of section 1877(e)(2) provided that an arrangement between a hospital and a physician (or the physician's immediate family member) for the employment of the physician (or family member) or for the provision of administrative services would not trigger the prohibition on referrals if certain conditions (detailed in the March 1992 proposed rule) were met. OBRA '93 amended this exception to make it applicable to any bona fide employment relationship with any employer that meets the same conditions.

d. Exception—Personal Service Arrangements

The predecessor provision of section 1877(e)(3) provided that remuneration from service arrangements with entities (other than hospitals) does not constitute a compensation arrangement for purposes of the prohibition on referrals if certain conditions (detailed in the March 1992 proposed rule) are met. This exception was limited to an arrangement for one of five specific types of services. OBRA '93 amended this provision to specify that remuneration from any entity under any kind of personal service arrangement (including remuneration for specific physicians' services furnished to a nonprofit blood center) would not constitute compensation that would trigger the prohibition on referrals if the following conditions are met:

- The arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement.
- The arrangement covers all of the services to be furnished by the physician (or immediate family member of the physician) to the entity.
- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.
- The term of the arrangement is for at least 1 year.
- The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value and, except in the case of a physician incentive plan (as described below), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.
- The arrangement meets any other requirements the Secretary may impose by regulation as needed to protect against Medicare program or patient abuse.

Section 1877(e)(3)(B) provides that, in the case of a physician incentive plan between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account, directly or indirectly, the volume or value of any referrals or other business generated between the parties if the plan meets the following requirements:

- No specific payment is made (directly or indirectly) under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the entity.
- If the plan places a physician or a physician group at substantial financial risk as determined by the Secretary under section 1876(i)(8)(A)(ii), the plan complies with any requirements the Secretary may impose under that section.

In addition, section 1877(e)(3)(B)(i)(III) requires the entity, upon request by the Secretary, to provide access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements listed above.

Section 1877(e)(3)(B)(ii) defines a ''physician incentive plan'' as any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the entity.

On December 14, 1992, we published, at 57 FR 59024, our proposed rule on physician incentive plans. Because there may be entities that were not affected by the proposed rule at the time it was published but are now affected, we plan to publish the final rule with a 60-day comment period so that these newly-affected entities have an opportunity to comment.

As the result of section 152(c) of SSA '94, until January 1, 1995, the provisions in section 1877(e)(3) do not apply to any arrangements that meet the requirements of subsection (e)(2) or (e)(3) of section 1877 of the Act before they were amended by OBRA '93.

e. Exception—Remuneration Unrelated to Provision of Clinical Laboratory Services

Before OBRA '93, section 1877(b)(4) provided an exception for financial relationships (ownership/investment interests or compensation arrangements) with a hospital unrelated to the provision of clinical lab services. OBRA '93 omits this exception, but replaces it with section 1877(e)(4), which excepts remuneration provided by a hospital to a physician if it is unrelated to the provision of clinical laboratory services. Section 152(c) of SSA '94 amends section 13562(b)(2)(B) of OBRA '93 to reinstate, until January 1, 1995, section 1877(b)(4) as it appeared before OBRA '93.

f. Exception—Physician Recruitment

OBRA '93 retains, at section 1877(e)(5), the provision previously at section 1877(e)(4). The provision provides that remuneration from a hospital to a physician to induce the physician to relocate to the area serviced by the hospital in order to be a member of the hospital's medical staff does not constitute a compensation arrangement for purposes of the prohibition on referrals if certain conditions (detailed in the March 1992 proposed rule) are met.

g. Exception—Isolated Transaction

OBRA '93 retains, at section 1877(e)(6), the provision previously at section 1877(e)(5). The provision provides that an isolated financial transaction, such as a one-time sale of property or (as added by OBRA '93) a practice, is not considered to be a compensation arrangement for purposes of the prohibition on referrals if certain conditions (detailed in the March 1992 proposed rule) are met.

h. Salaried Physicians in a Group Practice

OBRA '93 removed, effective January 1, 1992, the provision previously at section 1877(e)(6). That provision had specified that a compensation arrangement involving payment by a group practice of the salary of a physician member of the group practice did not constitute a compensation arrangement that would trigger the prohibition on referrals.

i. Exception—Certain Group Practice Arrangements With a Hospital

OBRA '93 added a new section 1877(e)(7) that provides, effective January 1, 1992, that an arrangement between a hospital and group under which clinical laboratory services are furnished by the group but are billed by the hospital does not constitute a compensation arrangement for purposes of the prohibition on referrals if the following conditions are met:

- With respect to the services furnished to a hospital inpatient, the arrangement is in accordance with the provision of inpatient hospital services under section 1861(b)(3).
- The arrangement began before December 19, 1989, and has continued in effect without interruption since that date.
- With respect to the clinical laboratory services covered under the arrangement, substantially all of these services furnished to patients of the hospital are furnished by the group under the arrangement.
- The arrangement is set out in a written agreement that specifies the services to be furnished by the parties and the amount of compensation.
- The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- The compensation is provided under an agreement that would be commercially reasonable even if no referrals were made to the entity.
- The arrangement between the parties meets any other requirements the Secretary may impose by regulation as needed to protect against Medicare program or patient abuse.

j. Exception—Payments by a Physician for Items and Services

OBRA '93 added a new section 1877(e)(8), which provides that the following do not constitute compensation arrangements for purposes of the prohibition on referrals:

- Payments made by a physician to a laboratory in exchange for the provision of clinical laboratory services.
- Payments made by a physician to an entity as compensation for items or services other than clinical laboratory services if the items or services are furnished at fair market value.

8. Sections 1877(f) and 1877(g)

SSA '94 amends the provisions of section 1877(f), which concern reporting requirements. This section requires each entity providing covered items or services for which payment may be made under Medicare to provide the Secretary with information concerning the entity's ownership, investment, and (as added by SSA '94) compensation arrangements including (1) the covered items and services furnished by the entity and (2) the names and unique physician identification numbers of all physicians with an ownership or investment interest (as described in section 1877(a)(2)(A)) in or a compensation arrangement (as described in section 1877(a)(2)(B)) with the entity, or whose immediate relatives have such an ownership or investment interest in or who have such a compensation relationship with the entity. OBRA '93 retained the provisions of section 1877(g), which concern sanctions.

9. Other Definitions

OBRA '93 amended section 1877(h)(5) and (6) to remove the definitions for ''investor'' and ''interested investor, disinterested investor,'' effective January 1, 1992.

II. Published Federal Register Documents

A. Provisions of the Proposed Rule—Physician Ownership of, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services

As stated earlier, on March 11, 1992, we published in the **Federal Register** a proposed rule that set forth our proposal for establishing in regulations the provisions of section 1877, as amended by OBRA '90, that relate to physician referrals to clinical laboratories. Section 1877 is very specific. For the most part, we believed the definitions set forth in section 1877(h) were detailed and therefore did not require extensive elaboration in regulations. Accordingly,

we proposed to adopt some of the statutory definitions, as well as some other provisions of section 1877, virtually unchanged from what the statute provided. To establish these rules in our regulations, we proposed to create a new subpart J under 42 CFR part 411 and to make conforming changes as discussed below.

1. Scope

We proposed to cite section 1877 as the statutory authority for the rule.

2. Definitions

In section 411.351, we proposed to establish definitions of certain terms based on definitions or descriptions given in section 1877: compensation arrangement, employee, fair market value, financial relationship, group practice, interested investor, investor, referral, and remuneration. In addition, we proposed to add other definitions: entity, immediate family member or a member of a physician's immediate family, practice, and referring physician.

For purposes of identifying financial relationships that may trigger the statutory prohibition on referrals under Medicare, we proposed to adopt the description of ownership and investment interests and compensation arrangements contained in sections 1877(a)(2) and (h)(1). We also proposed to include indirect financial relationships in the statutory prohibition on referrals under Medicare.

3. General Prohibition on Referrals

In section 411.353(a), we proposed that, unless permitted under an exception, a physician who has a financial relationship with an entity (or who has an immediate family member who has a financial relationship with an entity) may not make a referral to that entity for the furnishing of clinical laboratory services covered under Medicare beginning January 1, 1992. (Note that we are providing a 30-day delay of the effective date for the provisions of this final rule with comment. However, this does not delay the effective date for any of the provisions in the final rule that only reiterate the language in section 1877 of the Social Security Act. These provisions are effective according to their statutory effective dates. The effective date for this final rule with comment is, in essence, the effective date for those parts of the rule that interpret the statute.)

To inform the public of what entities we would consider entities that perform clinical laboratory services and, therefore, subject to the provisions of section 1877 and to the regulation, we referenced existing section 493.2, which defines a ''laboratory.''

We proposed, in section 411.353(b), that an entity that furnishes clinical laboratory services under a prohibited referral may not bill the Medicare program or any individual, third party payer, or other entity.

In section 411.353(c), we provided that we would not pay for a clinical laboratory service that is furnished under a prohibited referral, and we proposed, in section 411.353(d), to require an entity that collects payment for a laboratory service performed under a prohibited referral to refund all collected amounts on a timely basis.

4. Exceptions That Apply to Specific Services

In accordance with section 1877(b), we proposed, in section 411.355, that the prohibition on clinical laboratory referrals would not apply in the following circumstances:

- If a physician service is provided personally by (or under the direct personal supervision of) another physician in the same group practice as the referring physician.
- If an in-office ancillary service is performed personally by the referring physician, a physician who is a member of the same group practice as the referring physician, or a nonphysician employee of the referring physician or group practice who is personally supervised by the referring or group practice physician and—
  + The in-office ancillary service is performed either in a building where the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of clinical laboratory services; or in a building that is used by the group practice for centrally furnishing the group's clinical laboratory services; and
  + The in-office ancillary service is billed by the physician who performed or supervised the laboratory service; by the group practice in which the physician is a member; or by an entity that is wholly owned by the physician or physician's group practice.
- If the services are furnished to prepaid health plan enrollees by one of the following organizations: (1) A health maintenance organization or a competitive medical plan in accordance with a contract with us under section 1876; (2) a health care prepayment plan in accordance with an agreement with us to furnish the services to Medicare beneficiaries under section 1833(a)(1)(A); or (3) an organization that is receiving payments on a prepaid basis for the enrollees under a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 note).

We also proposed, in section 411.355(a), to use an existing definition of ''physicians' services'' but cited an incorrect cross reference to that definition. The cross-reference should have been to section 410.20 rather than section 411.20(a). Existing section 410.20 describes physicians' services and specifies the professionals who are considered to be ''physicians'' if they are authorized under State law to practice and if they act within the scope of their licenses.

5. Exceptions for Certain Ownership or Investment Interests

a. Publicly Traded Securities

We proposed, in section 411.357(a), that the prohibition on referrals would not apply to a physician's referrals if the financial relationship between the physician (or the physician's immediate family member) and the entity results from the ownership of certain investment securities. We proposed that the securities must be purchased by the physician (or immediate family member) on terms generally available to the public and be in a corporation that meets specific criteria.

b. Specific Providers

In section 411.357(b)(1), we proposed that the prohibition on referrals would not apply to a laboratory that is located in a rural area if certain criteria are met.

To supplement the statutory provision excepting services furnished in a rural laboratory, we proposed two requirements intended to address the possibility that this exception would be misused. First, we proposed to require, when physician owners or investors make referrals to a laboratory located in a rural area, that the tests be performed directly by the laboratory on its premises. We stated that, if referral to another laboratory is necessary, the test must be billed by the laboratory that performs the test. Second, we proposed to require that the majority of the tests referred to the rural laboratory be referred by physicians who have office practices in a rural area. (For this purpose, as indicated earlier, we proposed a definition of ''practice.'')

We proposed, in section 411.357(b)(2) and (b)(3), that the prohibition on referrals would not apply if the ownership or investment interest is in—

A hospital located in Puerto Rico; or

A hospital located outside of Puerto Rico if one of two specified conditions is met concerning the nature of the ownership.

6. Exceptions Related to Compensation Arrangements

We proposed to add section 411.359 to specify that, for purposes of the referral prohibition, certain compensation arrangements (as defined in the proposed rule) would not constitute a financial relationship if they involve—

- Rental or lease of office space;
- Certain employment and service arrangements with hospitals;
- Certain arrangements connected with physician recruitment;
- Certain isolated financial transactions;
- Certain service arrangements with entities other than hospitals;
- Salaried physicians in a group practice; and
- Other arrangements with hospitals if the arrangement does not relate to furnishing clinical laboratory services.

B. Provisions of the Interim Final Rule With Comment Period—Reporting Requirements for Financial Relationships Between Physicians and Health Care Entities That Furnish Selected Items and Services

The interim final rule with comment period (published December 3, 1991) listed reporting requirements under the Medicare program for the submission by certain health care entities of information about their financial relationships with physicians. It implemented section 1877(f), which includes the requirement that entities furnishing Medicare covered items or services provide us with information concerning their ownership or investment arrangements. (The rule extended the reporting to include compensation arrangements, not just ownership and investment interests.) The December 1991 interim final rule also provided notice of our decision to waive the requirements of section 1877(f) with respect to certain entities that do not furnish clinical laboratory services.

The information submitted was to include at least the name and unique physician identification number (UPIN) of each physician who had a financial relationship with the entity, the name and UPIN of each physician who had an immediate relative who had a financial relationship with the entity and, with respect to each physician identified, the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement, if we requested it).

Any person who, although required to, failed to submit the required information was subject to a civil money penalty of not more than $10,000 for each day of the period beginning on the day following the applicable deadline established until the information was submitted.

In addition, the interim final rule discussed our decision to waive the reporting requirements for all entities (other than those providing clinical laboratory services) in States other than the minimum number of 10 specified in the statute. In the 10 States we selected, the reporting requirements were waived for entities other than the 6 types enumerated in the statute and section 411.361(c). The waiver represented a balance between our need to obtain sufficient ownership information for meaningful use in developing a statistical profile required by the Congress in section 6204(f) of OBRA '89, as amended by section 4207(e)(4) of OBRA '90, and in evaluating the need for future legislative, policy, or operational actions, and the need to minimize the administrative time and cost involved in collecting and analyzing the information. We believe that by collecting the information from the enumerated entities in the minimum number of 10 States, we satisfied these congressional and administrative needs.

In determining the States in which a blanket waiver would not be granted, we selected 10 States that represented approximately 42 percent of the physicians who bill the Medicare program for items and services furnished to beneficiaries. Medicare contractors servicing all providers and suppliers in the 10 selected States process approximately 40 percent of all Medicare claims. Services provided by the six types of entities specified in the statute account for a significant proportion of Medicare expenditures and represent a cross-section of Medicare covered services. Therefore, we decided to waive the requirements of section 1877(f) with respect to entities (other than those providing clinical laboratory services) in all States except the following: Arkansas, California, Connecticut, Florida, Michigan, Ohio, Pennsylvania, South Carolina, Texas, and West Virginia. These States were selected because they represent: A mix of rural (West Virginia), urban (Florida), and mixed urban/rural States (Ohio, Texas); a variety of claims/bills volume, from very small (Arkansas) to very large (Pennsylvania); and, a geographic spread from north (Michigan) to south (South Carolina) as well as both coasts (from California to Connecticut).

Note that while the effect of section 1877(f) of the Act and section 6204(f) of OBRA '89 was to require the Secretary to submit to the Congress a statistical profile within 90 days after each calendar quarter, section 4207(e)(4) of OBRA '90 amended OBRA '89 to require only one statistical profile, which was due by June 30, 1992. Clinical laboratory entities reported information about financial relationships with physicians as part of a survey conducted in the fall of 1991, and we used this data in the required statistical profile.

Section 1877(f) authorizes the Secretary to gather information from any entity providing covered items or services in such form, manner, and at such time as she specifies. Thus, the Secretary can again require entities to report whenever she deems it appropriate for purposes of enforcing the referral prohibition in section 1877. Section 152(a) of SSA '94 amended section 1877(f), altering the rules for future reporting. The provision now requires entities to report not only their ownership arrangements with physicians, but also their investment and compensation arrangements. Section 152(a) also eliminated the Secretary's authority to waive the reporting requirements for certain states or services. The Secretary, however, continues to have the right to determine that an entity is not subject to the reporting requirements because it provides Medicare-covered services very infrequently. In addition, the reporting requirements still do not apply to designated health services furnished outside the United States. The effective date of the amendments to section 1877(f) is the date of enactment of SSA '94, that is, October 31, 1994.

III. Principles for Developing This Final Rule With Comment Period

In this final rule with comment, we are adopting the provisions of our March 1992 proposed rule, changed as appropriate to address the comments on the proposed rule and the new requirements relating to clinical laboratory services contained in OBRA '93, as amended by SSA '94, that have a retroactive effective date of January 1, 1992. OBRA '93 provides several exceptions that were not in previous legislation. In some cases, these new exceptions address suggestions received through public comment on the March 1992 proposed rule. It is our intention that this final rule with comment reflect, to the extent possible, the comments on the proposed rule and the new, but retroactive, requirements of OBRA '93,

as amended by SSA '94. This final rule with comment also revises the provisions of the December 1991 interim final rule to incorporate the amendments to section 1877(f) made by SSA '94, to apply to any future reporting that we require.

To address the provisions of section 1877 that are effective on January 1, 1995, as provided by OBRA '93, we plan to publish regulations in addition to this one. We will publish a proposed rule to interpret any retroactive provisions contained in OBRA '93 that we believe allow us to exercise discretion in their implementation. In this final rule, we have, in general, only reiterated the new, but retroactive, statutory provisions, incorporating them into our proposals. We have interpreted the new provisions only in the few instances in which it was necessary to do so in order to allow the statute to be implemented at all.

The proposed rule will also cover those provisions of section 1877 concerning physician referrals for clinical laboratory services that became effective on January 1, 1995, as well as those covering the other designated health services (all of which are effective for referrals made on or after January 1, 1995). Finally, we plan to publish a final rule that will address any comments received on this final rule with comment and the new proposed rule.

We are including in this final rule the OBRA '93 provisions related to the following:

- The in-office ancillary services exception.
- The rental of equipment exception.
- The rental of office space exception.
- The bona fide employment relationships exception.
- The personal services and physician incentive plan exception.
- The exception concerning remuneration unrelated to the provision of clinical laboratory services.
- The change in the isolated transactions exception.
- The exception concerning certain group practice arrangements with a hospital.
- The exception for payments by a physician for items and services.
- All changes in definitions in 1877(h) that have a retroactive effective date (compensation arrangement, remuneration, group practice).

IV. Analysis of and Responses to Public Comments on the Proposed Rule—Physician Ownership of, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services

In response to the publication in the **Federal Register** of the proposed rule on March 11, 1992, we received 299 timely public comments. The comments came from a wide variety of correspondents including professional associations and societies, health care workers, law firms, third party health insurers, hospitals, and private individuals. We screened each commenter's letter and grouped like or related comments. Some comments were identical, indicating that the commenters had submitted form letters. After associating like comments, we placed them in categories based on subject matter or based on the portion of the regulations affected and then reviewed the comments. All comments relating to general subjects, such as the format of the regulations, were similarly reviewed.

This process identified areas of the proposed regulation that we needed to review in terms of their effect on policy, consistency, or clarity of the rules.

We have presented all comments and responses in, for the most part, the order in which the issues appeared in the March 1992 proposed rule.

Note: We have found it necessary to change the designation of some sections from what was proposed. We have prepared a table, which appears at the end of this preamble, that relates the requirements in this final rule to the correlative proposed sections from which they evolved. If OBRA '93 provisions resulted in significant change, we so identify OBRA '93 as the source. This table is intended merely to assist parties who may be interested in comparing specific provisions as proposed or as contained in OBRA '93 to those of the final rule with comment. It does not supplant the more detailed discussion in this preamble. Unless otherwise indicated, citations in the responses that follow are to the sections as they are designated by this final rule with comment.

A. General

1. Purpose of Final Rule

Comment: One commenter requested that the Secretary ensure that the final rule is cast so that its purpose is clear; that is, the rule should be presented so as to support the idea that the ethical delivery of quality, medically necessary care is fundamental to preserving the integrity of medical practice in general as well as the Medicare program in particular.

Response: We share the commenter's view. We believe that section 1877 was enacted out of concern over the findings of various studies that physicians who have a financial relationship with a laboratory entity order more clinical laboratory tests for their Medicare patients than physicians who do not have a financial relationship. There have been at least 10 studies conducted over the past few years that concluded that patients of physicians who have financial relationships with health care suppliers receive a greater number of health care services from those suppliers than do patients generally.

To the extent that section 1877 and this final rule protect against this practice, the Medicare program and its beneficiaries are well served. Therefore, to the extent that physicians and providers of clinical laboratory services change their financial relationships and behavior to comply with provisions of section 1877 and, in turn, reduce overutilization of laboratory services, we believe that this change will have a positive effect on other health insurance programs. One of our prime goals is to ensure that our rules carry out the Congress' mandate in a manner that is in the best interest of all individuals who may be affected by the rules.

2. Delay of Effective Date

Comment: Several commenters requested that we delay the effective date of the final rule. One commenter recommended a 60-day delay, another recommended not less than 90 days, and yet another commenter requested not less than 120 days from the date of publication in the **Federal Register** and that application of the regulation should be prospective only.

Response: We usually provide for a 30-day delay in the effective date of a final rule. This delay is offered so that affected parties have the opportunity to change their practices, if necessary, to comply with the requirements of the final rule. While we understand that the goal behind the commenters' suggestions is to provide sufficient time for parties affected by this final rule to make arrangements to comply with its requirements, we do not believe that an additional delay in the effective date would be beneficial. This is so primarily because, in this rule, we are establishing additional exceptions from the prohibition on referrals based upon public comments. In addition, we plan to publish a subsequent final regulation that will address any comments received on this regulation.

3. Delay of Enforcement Provisions

Comment: One commenter requested that the Secretary indicate that the enforcement of the prohibition on referrals begin no earlier than the effective date of this rule. As a result of

this suggestion, any physician who is out of compliance with section 1877 before that effective date would be held harmless under the final rule.

Another commenter requested that we postpone the implementation of sanctions, at the very least, until 90 days after the final rule has been issued.

Response: Section 1877(g) of the Act sets forth several enforcement provisions that apply to prohibited referrals for clinical laboratory services and to prohibited claims for payment for these services.

- Section 1877(g)(1) provides for denial of Medicare payment for a clinical laboratory service furnished as the result of a prohibited referral.
- Under section 1877(g)(2), if a person collects any amounts that were billed for services furnished under a prohibited referral, a timely refund of each amount is required.
- Section 1877(g)(3) authorizes the imposition of civil money penalties of not more than $15,000 for each such service and possible exclusion from the Medicare and other programs for any person that presents, or causes to be presented, a bill or a claim for a clinical laboratory service that the person knows or should know was unlawfully referred or for which a refund has not been made.
- Under section 1877(g)(4), civil money penalties of not more than $100,000 for each arrangement or scheme and possible exclusion from participation in the Medicare and other programs are authorized in cases in which a physician or an entity enters into a circumvention arrangement or scheme (such as a cross-referral arrangement) that the physician or entity knows or should know has a principal purpose of ensuring referrals by the physician to a particular entity that would be unlawful under section 1877 if made directly. (See the final rule with comment published by the Office of Inspector General on March 31, 1995 (60 FR 16580) for further information. That rule addresses sections 1877(g)(3) and (g)(4).)

The first commenter appears to be suggesting that these statutory enforcement provisions should not be applied until the effective date of this final rule and that a physician who is not in compliance with the provisions of the statute at the time the final rule is published should be held harmless until the effective date of the final rule. The second commenter suggested a 90-day delay in application of any sanctions following publication of the final rule.

We disagree with these suggestions. First, many of the provisions of section 1877 of the Act were effective on January 1, 1992, by operation of law. These provisions are, for the most part, self-implementing. This rule incorporates into regulations statutory requirements that are already in effect, clarifying or interpreting certain provisions, and exercising the Secretary's authority to promulgate additional exceptions through regulations. Even though the requirements of this final rule are effective later than the effective date of the statute, we cannot postpone the statutory effective date. Nonetheless, any sanctions that can be applied only as a result of the clarification or interpretation of the statute specified in this rule will, of course, be applied prospectively, beginning with the effective date of this rule.

Section 1877(f) of the Act sets forth certain reporting requirements with which entities were to comply by October 1, 1991. Under this authority, we conducted a survey in the fall of 1991 concerning physician ownership in, and compensation arrangements with, entities furnishing clinical laboratory services. Based on data gathered from that survey, Medicare carriers have already been denying some claims for laboratory services furnished by a laboratory that is independent of a physician's office and that are furnished in violation of the prohibition on referrals. Similarly, the Office of the Inspector General could impose sanctions if, for example, a clinical laboratory has failed to refund an amount that it collected for a service furnished as the result of a referral if the laboratory knew the referral was prohibited.

4. Good Faith Standard

Comment: One commenter suggested that the final rule have either a good faith standard or a provision that the statute will not be violated unless the physician or the laboratory has actual knowledge of a prohibited referral. The commenter requested that the final rule specify the scope of the inquiry required and define the extent of the duty imposed upon laboratories and physicians to determine the relationship of persons that would affect their ability to refer laboratory work or to accept a referral.

Response: It is important to emphasize that the statute and this rule do not prohibit financial relationships that exist or might be established between physicians and entities providing clinical laboratory services. What is prohibited are certain referrals for clinical laboratory testing of Medicare patients. The statute itself, at section 1877(a)(2), describes ''financial relationship'' for purposes of determining whether a referral is prohibited. And, as discussed above, section 1877(g) specifies several sanctions that may be applied if a physician or an entity billing for a Medicare covered clinical laboratory service violates the statute's requirements. Thus, unless an exception applies, the statute operates automatically under its own terms to prohibit referrals for Medicare-covered clinical laboratory services to be performed by an entity with which the physician or an immediate family member of the physician has a financial relationship.

We understand that this commenter is advocating adoption of a policy that would hold harmless a physician or laboratory if there is no intention on the part of either to seek an advantage from an ownership interest or compensation arrangement. The commenter is also concerned that a physician or a laboratory may be unintentionally involved in a relationship that would call the physician's referrals into question. Similarly, a laboratory may be unaware that it has a relationship with a referring physician's relatives that would cause the prohibition to apply. However, the statutory prohibition against referrals in such situations applies because of the existence of the financial relationship, not because of the intent of the physician or laboratory or because there is actual knowledge of the relationship. It is the responsibility of physicians and laboratory entities to take whatever steps are necessary to ensure that they do not violate Federal law.

5. Physician Ownership of Health Care Facilities

Comment: One major national medical organization indicated that it believed ownership of health care facilities by referring physicians is an issue that should be addressed, and it supported the proposed rule. It believed there is increased evidence that, when physicians have a financial relationship with an entity, the relationship adversely affects patient care and adds to the cost of health care in the United States. Therefore, the organization believed that physicians should not have a direct or indirect financial interest in diagnostic or therapeutic facilities to which they refer patients, and it indicated support for legislation and regulations that would eliminate this conflict of interest by prohibiting such ownership arrangements in health care.

Response: We agree with this commenter. As stated earlier, recent studies have concluded that there is a higher level of utilization of services when physicians refer patients to entities with which they have a financial relationship. As mentioned in the preamble to the proposed rule (57 FR 8589), a report from the Office of the Inspector General to the Congress established that at least 25 percent of the nearly 4500 independent clinical laboratories are owned in whole or in part by referring physicians. The same report found that Medicare patients of referring physicians who own or invest in independent clinical laboratories received 45 percent more clinical laboratory services than all Medicare patients. (''Financial Arrangements Between Physicians and Health Care Businesses,'' May 1989, page 18). A study published in ''Medical Care'' (Vol. 32, No. 2) in February 1994 found that a review of clinical laboratory practices in Florida lends support to the contentions of critics that physician joint ventures (health care businesses that physicians own, but where they do not practice or directly provide services) result in increased use of services and higher charges to consumers. Utilization, measured as the number of billable laboratory procedures per patient, is significantly higher in facilities owned by referring physicians. Although the study reported only negligible differences in charges per procedure (compared to nonphysician-owned facilities), it found that higher utilization rates resulted in significantly higher gross and net revenue per patient. Furthermore, the study found that differences in average production costs per patient in physician-owned and nonphysician-owned facilities were not significant. The net result is that physician joint ventures are far more profitable than comparable nonphysician joint ventures. The study results, which included laboratory services furnished to both private and publicly insured patients, corroborate previous evidence of higher use of laboratory procedures among Medicare and Medicaid patients treated by referring physician investors.

Many States have enacted or are considering regulations that would affect physician referrals to entities with which the physicians have financial relationships. For example, New Jersey implemented regulations that effectively prohibit physicians from referring patients to facilities they own. Physicians who do not comply with the regulations are subject to sanctions under the State's physicians practice law. Furthermore, in OBRA '93 the Congress has extended application of the prohibition on referrals to other types of health care services and health care entities.

6. Process for Amending Regulations

Comment: One commenter indicated that we should maintain an expedited process for amending the regulations and issuing clarifications. The commenter pointed out that, despite a careful review of the proposed regulations, it is not possible to identify all of the unintended consequences of applying the proposed regulations to particular laboratory arrangements. The commenter believed that unless we respond quickly to issue clarifications and correct such problems when identified, inappropriate regulations can disrupt the delivery of, and limit patient access to, quality clinical laboratory services.

Response: We understand and appreciate the commenter's desire to feel secure about the requirements of the law. We make all possible efforts to publish final rules as quickly as possible and to amend the regulations expeditiously if clarifications or changes are needed and can be accomplished through rulemaking. In addition, we keep our regional offices and the Medicare contractors informed through manual instructions of technical changes that can be made without rulemaking. The contractors, in turn, advise the physicians and laboratory entities in their service areas of such changes. In regard to inquiries about particular laboratory arrangements, our regulations do not provide for the issuance of formal advisory opinions of any kind pertaining to section 1877 or any other section of the law for which we are responsible. We receive a large volume of correspondence from the public, and we do respond to general questions about the contents of our regulations and manuals. We, however, do not have the authority and will not attempt to interpret the applicability of these physician self-referral provisions to situations posed in correspondence. Our advice must, of necessity, continue to be general.

7. Evolution of Group Practices

Comment: Before the enactment of section 1877 of the Act, the Medicare program did not have a statutory definition of ''group practice,'' nor any detailed body of law developed through regulations or manual instructions to define or otherwise recognize a group practice as a provider entity. One commenter indicated that we should recognize the significance of this rulemaking to the development and evolution of group practices in this country.

The commenter expressed hope that regulations will recognize the diversity of business structures within the group practice field and accommodate nonabusive arrangements for the provision of clinical laboratory services based on the substance of the arrangements, not merely their form.

The commenter also indicated that we should be mindful of the significance of this rule to the competitive ''playing field'' in health care. It was stated that, as medical group practices evolve into larger and more full-service providers of a wide range of physician ancillary and other health care products and services, they are furnishing many items and services that have traditionally been furnished by inpatient institutions or independent suppliers. The commenter also expressed hope that nothing in the final rule will prohibit group practices from performing services for other physicians' patients or other providers assuming, of course, that the referring source does not have a prohibited financial arrangement with the group. The commenter applauded us for proposing a rule that does not force groups to choose between serving their own patients and those of otherwise unrelated physicians.

Response: In publishing these final regulations, it is not our intent to obstruct the efforts of an association of physicians to qualify as a group practice under the definition in section 1877(h)(4) and therefore qualify for the in-office ancillary services exception set forth in section 1877(b)(2) of the Act and described in § 411.355(b). If a group of physicians meets the definition of a ''group practice'' under section 1877(h), it could also be eligible for the exception for physicians' services in section 1877(b)(1) and possibly the exception in section 1877(e)(7) for certain arrangements between a hospital and a group practice. Further, we believe that, to the extent possible, we have accommodated various group practice configurations given the statutory parameters.

The point made in the last sentence of the comment, as we understand it, endorses the adoption of a policy that would enable group practice laboratories to continue to perform laboratory tests for their own patients as well as to accept laboratory referrals from physicians in the community who do not have a financial relationship with the group practice. In the responses to various comments presented below, we have clarified that the provisions of section 1877 prohibit

laboratory referrals only if a financial relationship exists between the referring physician (or an immediate family member) and the laboratory entity. In other words, the law does not prohibit a laboratory from accepting referrals from a physician who does not have a financial relationship with it. Therefore, in all situations, a group practice will be permitted to accept referrals for laboratory services from physicians in the community who do not have, or do not have an immediate family member who has, a financial relationship with the group practice or the laboratory.

8. Use of Diagnosis Code for Laboratory Billing

Comment: One commenter believed the government is being misled about the need for certain diagnostic testing. The commenter noted that self-referrals could be used by unscrupulous physicians as a means to generate income. The commenter believed a major check on this practice would be the requirement of an appropriate diagnosis code for each service billed. The commenter believed it should be the role of the Medicare carriers to monitor unnecessary testing and then to take appropriate actions so that no testing is paid for if the diagnosis code does not suggest medical need.

Response: Section 202(g) of the Medicare Catastrophic Coverage Act of 1988 (Public Law 100–360), enacted July 1, 1988, added paragraph (p) to section 1842 of the Act. Under the provisions of section 1842(p)(1), each bill or request for payment for physicians' services under Medicare Part B must include the appropriate diagnosis code ''as established by the Secretary'' for each item or service the Medicare beneficiary received. We fully explain the conditions and requirements of this provision in a final rule published on March 4, 1994 (59 FR 10290).

The conference report that accompanied Public Law 100–360 explained clearly the purpose of the requirement for physician diagnostic coding. After rejecting a Senate provision that would have required the use of diagnostic codes on all prescriptions, because they believed that the requirement would have been unduly burdensome on Medicare suppliers of services, the conferees agreed to require diagnostic coding for physicians' services under Part B. They explained their reasons for this requirement as follows: ''This information would be available for immediate use for utilization review of physician services * * *.'' (H.R. Conf. Rep. No. 661, 100th Cong., 2nd Sess. 191 (1988)) The new coding requirement does not apply to bills from laboratories, except for physician laboratory services, which are described in section 405.556.

Claims submitted directly to the Medicare carrier by a clinical laboratory that is not part of a physician's office are not subject to the above requirement. The Medicare carriers, however, review claims submitted for payment to ensure that, to the extent possible, only services that are reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member are approved for payment. We agree that it would be easier for a Medicare carrier to make a medical necessity determination if the claim contained an appropriate diagnosis coding. It is clear, however, that the Congress intended to limit diagnosis coding to physicians' services. Therefore, at this time, we are unable to accept the suggestion the commenter made.

9. Referrals That Are Not Abusive

Comment: One commenter indicated that it would appear that relationships between a practitioner and an entity would not pose a risk of patient or program abuse if the relationships do not result in a return to the practitioner of monies beyond those that would be received if the physician directly furnished such laboratory tests (or other Medicare outpatient services).

The commenter suggested that it would be helpful if an exception could be established for referrals, from a physician to an entity, that are medically necessary (that is, represent legitimate claims on the Medicare program) and are not motivated by direct or indirect financial benefits that exceed fair market value accruing to the physician.

Response: The commenter appears to argue that the prohibition should not apply to a referral that is made by a physician to an entity with which he or she has a financial relationship if the service being performed is determined to be medically necessary and the physician does not realize an unacceptable financial gain as a result of the laboratory referral. The financial gain could not be larger than the fair market value of what he or she would realize if the service was performed, for example, in his or her own office and would have qualified for the in-office ancillary services exception.

Section 1862(a)(1) states, in part, that, notwithstanding any other provision of title XVIII of the Act, no payment may be made under Part A or Part B of the Medicare program for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. In exercising their contractual responsibilities, Medicare carriers enforce this overriding coverage criterion through the use of claims screens, medical review, and other procedures. The commenter appears to believe that, because these carrier safeguards are in place, a ''reasonable and necessary'' exception could be established. The problem with this commenter's approach is twofold. First, section 1877 prohibits certain referrals to entities with which the referring physician or an immediate family member has a financial relationship regardless of whether the service furnished is found by a carrier to be medically necessary. Second, assessing whether a physician's referrals result in a financial gain from the relationship with a laboratory would be a very difficult and burdensome administrative process. Carriers process approximately 4 million claims for clinical laboratory services each year. It would be very costly to determine whether each claim called into question by certain referrals results in a cost benefit to the referring physician.

10. Contractor Implementation

Comment: One commenter, a Medicare contractor, indicated it had concerns with the administration of the prohibition on referrals along with the numerous exceptions that have been granted for specific services, certain ownership or investment interests, and certain compensation arrangements. The commenter anticipates that the monitoring of these various provisions will be complex and will greatly affect post-pay and systems areas.

Response: It is not clear, at this time, how significant a workload the provisions will create for carrier claims processing and fraud units. However, once this rule is published, the carriers will start performing compliance audits based on specified criteria. We do not expect that these audits will result in much increase in the carrier's workload. We do not believe that there will be any significant effect on either post-pay or systems areas.

B. Scope of Regulations

Comment: One commenter indicated that the preamble section of the proposed rule explaining what the agency believes is the regulatory scope (57 FR 8593) should be omitted. The commenter contended that it imparts no specific guidance and defines no

regulatory requirement. Furthermore, this commenter objected to the preamble reference to violations of other Federal or State law and stated that it is gratuitous to advise the regulated entity or person that compliance with section 1877 of the Act, or regulations promulgated thereunder, does not foreclose citation and adjudication under another Federal or State statutory requirement or regulation.

Response: We disagree. Sections 411.1 and 411.350, as described in the preamble of the proposed rule and as set forth in the proposed regulation, conform to regulation drafting guidelines in explaining the general content of 42 CFR part 411, subpart J. Our intent in including this information, something that is routinely done in any new HCFA regulation, is to provide the public with an outline of the regulation's substantive content.

In this case it is important as well to state what the new regulation does not provide for. Before the proposed rule was published, we received numerous inquiries indicating that the provisions of section 1877 were being confused with the anti-kickback safe harbors specified in the final rule published on July 29, 1991 (56 FR 35952). In fact, the Medicare anti-kickback statute (section 1128B(b) of the Act) and section 1877, while similar in that they address possible abuses of Medicare, are different in scope and application and, therefore, need to be distinguished. The conference report for OBRA '89 includes the following statement:

> The conferees wish to clarify that any prohibition, exemption, or exception authorized under this provision in no way alters (or reflects on) the scope and application of the anti-kickback provisions in section 1128B of the Social Security Act. The conferees do not intend that this provision should be construed as affecting, or in any way interfering, [sic] with the efforts of the Inspector General to enforce current law, such as cases described in the recent Fraud Alert issued by the Inspector General. In particular, entities which would be eligible for a specific exemption would be subject to all of the provisions of current law. (H.R. Conf. Rep. No. 386, 101st Cong., 1st session 856 (1989).)

Furthermore, we believe it is our duty to inform the public that lawful conduct under sections 1128B and 1877 of the Act may not be lawful under other Federal statutes or State law or regulations. Conversely, conduct that is lawful under those other authorities may be prohibited under section 1877 and these final regulations.

C. Definitions

1. Clinical Laboratory Services

Under the proposed rule (section 411.353), ''laboratory services'' are considered to be any services provided by the entities described in section 493.2. The preamble to the proposed rule pointed out at 57 FR 8595 that this would include anatomical laboratory services but would not include noninvasive tests that are not considered clinical laboratory services, such as electroencephalograms or electrocardiograms. Nor would it include x-rays or diagnostic imaging services, such as mammogram and computerized axial tomography scans.

Comment: A few commenters recommended that a definition of ''clinical laboratory'' be included in the regulations. They suggested that, if the definition used for purposes of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) is to be adopted, that it should be repeated in section 411.351.

One commenter indicated that the definition of clinical laboratory should state the following:

''Clinical laboratory means a facility for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, as described in section 493.2. Such examinations include screening procedures to determine the presence or absence of various substances or organisms in the body. Such examinations do not include noninvasive tests, such as electroencephalograms, electrocardiograms, x-rays or diagnostic imaging services, such as mammogram and computerized axial tomography services.''

Response: We agree that this final regulation should contain a definition of clinical laboratory. Thus, based on the definition at section 493.2, which defines a laboratory for CLIA purposes, we are including the following in section 411.351:

> *Laboratory* means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Comment: One commenter urged that the definition of laboratory services should include a statement that what are considered clinical laboratory services for current procedural terminology (CPT) code purposes are also considered clinical laboratory services for the purpose of these regulations. Thus, in this commenter's opinion, there would be no question about what constitutes clinical laboratory services.

Response: As mentioned in the response to the previous comment, we have defined a clinical laboratory as meaning any laboratory entity that is required to satisfy the CLIA standards in order to perform tests on human beings for ''* * * the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.'' Therefore, for the purposes of the prohibition on physician self-referral, we are defining ''clinical laboratory services'' at section 411.351 as follows:

> *Clinical laboratory services* means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

Given this position, the American Medical Association (the organization responsible for CPT) and the CPT publication would not be the references to define the kind of services that are regulated by the physician referral legislation. If individuals want to know what specific tests and test systems are subject to CLIA certification, they may contact the Center for Disease Control and Prevention (CDC), Public Health Service, Attention: CLIA, 1600 Clifton Road, Atlanta, GA 30333. CDC has categorized approximately 12,000 test systems, assays, and examinations for complexity using the criteria at 42 CFR 493.17. CDC publishes notices periodically in the **Federal Register** to announce additional test systems, assays, or examinations that have been categorized or recategorized since the preceding publication.

For these reasons, we do not support the sole use of CPT codes to identify

clinical laboratory services for physician referral purposes.

Comment: One commenter suggested that it would be helpful to define further what type of anatomical laboratory services are covered by the statute and which specific tests we consider to be noninvasive and not subject to the prohibition on referrals.

Response: We agree with this commenter. As mentioned in the preamble to the proposed rule (57 FR 8595), anatomical laboratory services are subject to the prohibition on physician referrals. Anatomical laboratory services (and anatomical pathology services) involve the examination of tissue, often tissue removed during surgery. As such, it appears to us that anatomical laboratory services are always invasive (that is, they involve the examination of materials derived from the human body, as described in 42 CFR 493.2). Therefore, we believe that these tests would always be subject to CLIA and section 1877. Consequently, any physician who refers patients for these kinds of tests to a laboratory with which he or she (or a family member) has a financial relationship could be in violation of section 1877. In such a case, any of the many exceptions in section 1877 might exempt that physician's referral from the prohibition.

The commenter has also suggested that we specify which noninvasive testing is exempt from the prohibition on referrals. As mentioned in the response to the previous comment, we believe that the most appropriate way for a physician or clinical laboratory to determine if Medicare considers a diagnostic test to be a clinical laboratory test subject to the requirements of section 1877, is to find out if the test is subject to categorization under CLIA. The Medicare carriers are available to provide this information to individuals and physicians if it is not clear to a physician, other supplier, or provider of services and if they do not have available the latest compiled list of clinical laboratory test systems, assays, and examinations categorized by complexity and published by the CDC. If a test does not appear on a compiled list, a physician or laboratory should contact the CDC at the address we mentioned in the last response in order to be certain, since the lists are not yet complete.

2. Compensation Arrangement

Under the proposed rule (§ 411.351), a compensation arrangement would be any arrangement that involves any remuneration between a physician or a member of his or her immediate family and an entity. The definition of compensation arrangement was amended by OBRA '93 to exclude certain types of remuneration (identified in section I.D.1.c. of this preamble).

Comment: One commenter indicated that the final regulations need to give a specific definition for the phrase ''compensation arrangement,'' not simply repeat the words that the Congress has provided.

Response: The commenter did not explain why the proposed definition was perceived as insufficient. The words of the definition are specific, and we do not believe they are susceptible to misinterpretation. The definition is broad, because it covers any remuneration between a physician (or an immediate family member) and an entity, and it may be this aspect of the definition that concerned the commenter. We believe, however, that it was the intent of the Congress to include all arrangements (direct and indirect) between physicians and laboratories involving any remuneration. We believe that the statutory definition accomplishes this purpose. In the OBRA '93 amendments, the Congress retained the broad definition of ''remuneration'' in section 1877(h)(1)(B), but did specifically except from the term ''compensation arrangement'' a very limited list of arrangements involving the kinds of remuneration listed in section 1877(h)(1)(C). These changes are reflected in this final regulation.

Comment: One commenter indicated that laboratories often must enter into arrangements with physicians, who are not employed by the laboratory, for necessary services. The commenter believed that as long as certain safeguards, comparable to those applicable to arrangements between physicians and hospitals, are met, these arrangements should not be considered compensation arrangements that would prohibit the physicians from making referrals. Examples of such arrangements are (1) an arrangement to review abnormal test results when further medical consultation is required, and (2) a contract with a physician to provide various consultation services, such as reviewing anatomic pathology specimens, interpreting holter monitors or electrocardiograms, and reviewing Pap tests.

Another commenter indicated that, because of the breadth of the self-referral law, any time a laboratory makes a payment to a physician, a compensation arrangement is created. Thus, for example, if a laboratory maintains a self-insured group medical plan and pays physicians directly for the medical services provided to its employees, it would, in this commenter's view, have a compensation arrangement with those physicians and should not accept Medicare referrals from them. The commenter suggested that these types of legitimate arrangements should not be considered compensation arrangements as long as safeguards are put into place to ensure nonabuse.

Response: What these commenters are asking for is an exception for an arrangement under which a referring physician furnishes services to a laboratory (or, alternatively, that the term compensation arrangement be defined in a manner so as not to include that arrangement). Section 1877(e)(3), as amended by OBRA '93, provides an exception for a compensation relationship in which a laboratory entity pays a physician for personal services furnished under an arrangement. Such an arrangement does not result in the physician being prohibited from making referrals to that entity if certain specific conditions (detailed in section I.D.6.d. of this preamble) are met.

In addition to the exception in section 1877(e)(3), section 1877(e)(2), as amended by OBRA '93, provides that, if a laboratory makes payments to a physician as the result of a bona fide employment relationship with the physician, that physician's referrals would not be prohibited, providing certain criteria are met.

Comment: One commenter stated that in many situations laboratories are required by State or Federal law to have particular arrangements with physicians. For example, under the new CLIA regulations (42 CFR part 493), laboratories may be required to have physicians in a number of different positions in the laboratory. The commenter believed these types of arrangements should not be considered compensation arrangements that would prohibit referrals by the physicians.

Response: As mentioned in an earlier response, it is our belief that most of these arrangements could qualify for either the exception found in section 1877(e)(2) for bona fide employment relationships or, when the physicians are not employed, section 1877(e)(3) for personal service arrangements.

Accordingly, a compensation arrangement between a laboratory and a referring physician for specific identifiable services that has all of the elements required for the subject exceptions would not cause that physician's referrals to be prohibited.

Comment: One commenter noted that laboratories routinely sell services directly to physicians who then

reimburse the laboratory for those services before marking them up to patients. The commenter did not believe that those payments should constitute a compensation arrangement.

Response: As set forth in OBRA '93, section 1877(e)(8)(A) of the Act provides a compensation-related exception for physicians who pay a laboratory in exchange for the provision of clinical laboratory services (see section 411.357(i)(1)).

The commenter has made the point that physicians routinely reimburse laboratories for services and then mark them up to patients. Under section 1833(h)(5)(A), Medicare payment for a clinical diagnostic laboratory test may be made only to the person or entity that performed or supervised the performance of the test. (This rule is subject to certain exceptions involving services furnished or supervised by a physician when payment is made to another physician in the same group practice, services performed by a laboratory at the request of another laboratory, and tests performed under arrangements made by a hospital.) As a result, physicians should generally not be able to pay a laboratory in exchange for Medicare covered laboratory services, and then mark them up to patients.

Comment: One commenter noted that many laboratories are part of large, diversified corporations (which themselves may be related to other large, diversified corporations) that provide a number of different services to physicians. These services may include pharmaceutical, billing, and waste transport services. The commenter believed that, so long as these services are provided at fair market value, there is no reason that an entity should not provide these services to physicians and also accept their Medicare referrals.

Response: As mentioned previously, if a physician is paying fair market value to the supplier entity for whatever nonlaboratory services he or she is purchasing, referrals by the physician to the laboratory should not be prohibited. However, the arrangement must meet the conditions found in new § 411.357(i).

Comment: One commenter indicated that the regulations should be clarified to expressly prohibit any arrangement under which the referring physician bills patients for clinical laboratory or anatomic pathology services that are not personally performed or supervised by the billing physician or the group practice. In particular, the commenter suggested that the prohibition should apply to arrangements under which the referring physician requires the pathologist or independent laboratory to bill the referring physician, rather than the patient or third party payer, for any services provided by the pathologist or independent laboratory on referral by the physician. The commenter pointed out that, at the present time, the Medicare payment rules prohibit a physician from billing for certain clinical diagnostic laboratory tests performed by an independent laboratory for Medicare patients (section 1833(h)(5)(A)) but, the commenter maintained, this payment prohibition does not apply to anatomic pathology services or to clinical laboratory services performed for non-Medicare patients. Thus, the commenter concluded that the referring physician would not be prohibited from marking up the costs of anatomical tests to Medicare and for clinical laboratory and anatomical testing billed to other third party payers.

The commenter believed that an arrangement under which the referring physician charges payers for the services of a separate laboratory constitutes a compensation arrangement within the meaning of the law. The commenter added that ''compensation arrangement'' is defined as any arrangement ''involving any remuneration.'' Further, the term ''remuneration'' is defined broadly to include direct or indirect, overt or covert, and in-cash or in-kind arrangements. The commenter believed, therefore, that an arrangement under which the referring physician can receive payment for services not personally performed or supervised by himself or herself, including payment for services for non-Medicare patients, should be found to be a compensation arrangement within the broad language of the law.

Specifically, the commenter recommended that the final regulation make clear that the definition of ''compensation arrangement'' encompasses any arrangement under which a referring physician bills and collects for laboratory services that are not personally performed or supervised by the physician.

Response: This commenter raised several issues: first, whether anatomical pathology services are diagnostic laboratory tests and, thus, subject to the billing requirements of section 1833(h)(5)(A); second, whether the billing requirements of that section can be applied to clinical diagnostic laboratory tests performed for non-Medicare patients; and third, whether the definitions of compensation and remuneration at section 1877(h)(1) can be broadly interpreted to include payments made to the physician for any laboratory services he or she did not personally perform or supervise, including payment for services for non-Medicare patients. We will address each of these issues in order.

Under Medicare, the term ''medical and other health services'' includes, under section 1861(s)(3), the broad category of ''diagnostic laboratory tests.'' Under section 1861(s)(16), such diagnostic laboratory tests include only those diagnostic tests performed in a laboratory that meets CLIA requirements. Anatomical pathology services are tests involving tissue examination, such as that done during surgery. We believe that any anatomical pathology tests would be diagnostic in nature and would have to be performed in a laboratory that meets CLIA requirements. As such, the tests fall squarely within the category of ''diagnostic laboratory tests'' and would therefore be subject to the payment rules in section 1833(h)(5)(A).

Under section 1833(h)(5)(A), payments for clinical diagnostic laboratory tests are subject to mandatory assignment. That is, with certain narrow exceptions, payment may be made only to the person or entity that performed or supervised the performance of the test. Further, under section 1842(b)(6), a carrier generally may pay assigned benefits only to the physician or other supplier that furnished the service. Thus, unless physicians are billing Medicare within the conditions found in these provisions of the law, they are billing in error.

In regard to the second issue, the language of section 1833(h)(5)(A) applies specifically to services for which payment may be made under Medicare Part B. Therefore, we agree with the commenter that the billing requirements found in the Medicare statute do not extend to non-Medicare patients.

In regard to the third issue, under section 1877(e)(8)(A), payments by a physician to a laboratory for clinical laboratory services do not constitute compensation that triggers the referral prohibition.

3. Entity

In the proposed rule (§ 411.351), we defined ''entity'' as a sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association.

Comment: One commenter indicated that the statute does not define ''entity'' and the definition in the proposed regulations could prohibit certain nonabusive arrangements because it covers trusts, foundations, and not-for-

profit corporations. For example, a physician might own stock in a not-for-profit corporation or be a trustee of a charitable trust that operates a laboratory. The commenter suggested that this definition either be modified to contain an exception for nonabusive business entities or that the trust, foundation, and not-for-profit corporation criteria be deleted.

Response: We do not agree with this commenter. Under section 1877, unless an exception applies, any referral for clinical laboratory services is prohibited if the referring physician or a member of the physician's immediate family has a financial relationship with the entity to which the referral is made. This is so because the statute does not, in any way, limit the types of organizations covered by the referral prohibition as long as they provide clinical laboratory services. Therefore, our proposed definition of ''entity'' was meant to include all possible organizations and associations that provide laboratory testing. As was stated in the proposed rule, we believe that we need to define the term ''entity'' to ensure that the term is understood by all affected parties. Note, however, that if a trustee takes no compensation from and has no ownership interest in an entity, he or she would not have a financial relationship as defined in section 1877. Therefore, the physician would not be prohibited from referring Medicare patients to that entity. Finally, we are not aware of any situations in which a not-for-profit entity would issue stock.

4. Fair Market Value

Under the proposed rule (section 411.351), fair market value is defined to mean the value in arm's-length transactions, consistent with the general market value. With respect to rentals or leases, ''fair market value'' means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience of the lessor when the lessor is a potential source of patient referrals to the lessee. This definition is based on the definition in the statute. (OBRA '93 did not change the statutory definition.)

Comment: One commenter indicated that the statute makes it clear that lease and rental values may not be adjusted to reflect proximity to referral sources. The commenter was concerned about our statement in the preamble to the proposed rule at 57 FR 8599 that certain rental payments could be construed to induce referrals, even if there is no explicit or implicit understanding regarding referrals. These arrangements would typically involve rental payments either substantially above or below the fair market value of the rental space. The commenter believed that there is still no adequate means to determine when an increase (or decrease) in value will be considered ''substantial'' and therefore viewed as suspect. The commenter agreed that an example of an abusive arrangement occurs when a physician rents space to a health care entity at a rate above what the market would ordinarily bear, and the entity agrees to the high rent because of an understanding that the physician will refer his or her patients to that entity.

The commenter pointed out that many factors influence what may be considered as ''fair market value'' in a normally functioning real estate market. For example, the principle that site rents vary inversely with increased travel time pervades the real estate industry. Thus, the commenter concluded, a facility that is convenient to places in which health care services are furnished, such as a laboratory adjacent to a medical building, will command higher rents than one across town.

The commenter suggested that the final rule should reflect some means of differentiating between rent and lease payments that have inherently greater values based on traditional economic factors and those that are ''artificially'' inflated.

Response: In using the term ''substantially'' in excess of or below fair market value, we were describing an example of how a rental or lease agreement could be an influence on referrals. Such an agreement could take many forms and incorporate a myriad of possible financial incentives depending on local factors that could influence the rental or lease price. We want to emphasize, however, that the definitions in the statute (section 1877(h)(3)) and regulations (§ 411.351) state that fair market value means that a rental or lease of property must be consistent with the value of the property for general commercial purposes and that a rental or lease of space may not be adjusted to reflect any additional value a lessee or lessor would attribute to the proximity or convenience of a potential source of referrals. Therefore, if the economic factor to which the commenter referred, that is, that site rents vary inversely with increased travel time, plays a part in determining the level of rent agreed to by a physician and a laboratory entity, the fair market value test set forth in the statue would not be met. This would be the case even if the factor is a ''traditional economic factor'' that ''pervades the real estate industry.'' In other words, if rent is inflated either artificially or because of its proximity to a referral source, the fair market standard would not be met and the exception would not apply.

5. Financial Relationship

In the proposed rule (section 411.351), we defined a ''financial relationship'' as either a direct or indirect relationship between a physician (or a member of a physician's immediate family) and an entity in which the physician or family member has—

(1) An ownership or investment interest that exists through equity, debt, or other similar means; or

(2) A compensation arrangement.

The OBRA '93 amendments added that, in addition to equity, debt, or other means, an ownership interest includes an interest in an entity that holds an ownership or investment interest in any entity providing clinical laboratory services. This expanded provision, however, is not applicable until January 1, 1995.

Comment: One commenter expressed strong support for the proposed policy that the prohibition would extend to physicians who are the previous owners of a laboratory, if they are paid by the new owners under an installment sales agreement that extends past January 1, 1992. The commenter indicated that such arrangements can easily be abused; that is, they raise the possibility that the previous owners would make referrals for the purpose of ensuring that the new owners continue to pay off their debt. Similarly, the commenter agreed with our statement that, if an organization related to the laboratory agrees to pay the laboratory's debt to the physician, a financial relationship is still created.

On the other hand, another commenter indicated that we should permit specific debt relationships if the following criterion is met: The debt interest is manifested by a written note that has a fixed repayment schedule unrelated in any fashion to the productivity of the debtor or any entity owned by the debtor, and the debt-equity relationship of the debtor does not exceed 4 to 1.

Another commenter recommended that physicians who remain interested investors through a debt relationship in a laboratory that they once owned not be penalized. That is, the physicians should not be subsequently regarded as having a nonexempt financial relationship with that laboratory.

Response: We agree with the first commenter. A financial relationship may exist in the form of an ownership or investment interest, which, according to the language in section 1877(a)(2), ''may be through equity, debt, or other means.'' We did not propose any exceptions addressing situations involving debt. That is because we do not believe that there would be no risk of program or patient abuse in such circumstances. Obviously, the continued financial viability of an entity that is in debt to a potential referring physician could be of great concern to that physician. Therefore, we are not providing the exception requested.

Comment: Two commenters indicated that the term ''indirect relationship,'' which is used to define financial relationships in proposed § 411.351, should be itself defined or deleted since there is no statutory definition of indirect relationships. According to the discussion at page 8595 of the proposed rule's preamble, ''a physician would be considered to have an indirect financial relationship with a laboratory entity if he or she had an ownership interest in an entity which in turn has an ownership interest in the laboratory entity.'' The commenter stated that, if this is the definition we adopt, that definition should appear in § 411.351 of the final regulations; otherwise, the term should be deleted from the regulation entirely.

Response: We agree with the commenter that our interpretation of indirect ownership or investment interest should appear in the regulation. Therefore, we include it in section 411.351 of this final rule. As specified at section 1877(a)(2), financial relationships that could cause a referral to be prohibited are of two kinds. The first is an ownership or investment interest, which may be through equity, debt, or other means. The second is a compensation arrangement, which, as defined at section 1877(h)(1)(A), is any arrangement involving any remuneration (with certain narrow exceptions added by OBRA '93). ''Remuneration'' is defined in section 1877(h)(1)(B) as including *any remuneration*, direct or indirect, overt or covert, in cash or in kind. This is a broad concept that, we believe, encompasses compensation/remuneration obtained through an indirect financial arrangement. We further believe that an indirect relationship can occur in the ownership/investment situation as well as under a compensation arrangement. The term ''indirect'' appears specifically only in the definition of remuneration in section 1877(h)(1)(B), which applies in the context of compensation arrangements. However, an ownership or investment interest as defined in section 1877(a)(2) may be through equity, debt, or *other means.* We believe that the term ''other means'' is broad enough to encompass an infinite variety of direct and indirect ownership or investment interests. As a result, we included the concept of an indirect ownership or investment interest in the proposed rule.

It was also our opinion that the Congress intended to cover all forms of financial relationships that may exist between a physician and a laboratory. Any other reading would allow physicians to easily circumvent the statute: they could hold ownership interests in entities furnishing clinical laboratory services by simply establishing and owning shares in holding companies or shell corporations that, in turn, own the laboratories.

The Congress has demonstrated its intention to cover situations involving indirect ownership and investment interests. As amended by OBRA '93, the language at the end of section 1877(a)(2) provides that ''[a]n ownership or investment interest may be through equity, debt, or *other means, and includes* an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service.'' [Emphasis added.] This provision became effective January 1, 1995. However, we believe the amended provision demonstrates that, prior to OBRA '93, an ownership or investment held through ''other means'' could be interpreted to *include* indirect interests.

In addition, in proposing this amendment, the Committee on Ways and Means explained that ''[t]he definition of financial relationship would be modified to include *explicitly* that an interest in an entity (i.e., holding company) that holds an investment or ownership interest in another entity is a financial relationship for purposes of the referral prohibition.'' [Emphasis added.] (H. Rep. No. 111, 103d Cong., 1st Sess. (1993).) In other words, we believe the intent of this amendment was to explicitly list a concept that was already implicitly included in the scope of the provision. The Conference Report for OBRA '93 reveals that the House Ways and Means provision was enacted without changes. (H. Rep. No. 213, 103d Cong., 1st Sess. (1993).) For these reasons, we decline to delete the term ''indirect'' and intend that it be considered in determining whether particular referrals are prohibited.

6. Group Practice

Under the proposed rule (§ 411.351), a group practice means a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association that meets the following conditions:

- Each physician who is a member of the group furnishes substantially the full range of patient care services that the physician routinely furnishes including medical care, consultation, diagnosis, and treatment through the joint use of shared office space, facilities, equipment and personnel.
- Substantially all of the patient care services of the physicians who are members of the group (that is, at least 85 percent of the aggregate services furnished by all physician members of the group practice) are furnished through the group and are billed in the name of the group and the amounts received are treated as receipts of the group. The group practice must attest in writing that it meets this 85 percent requirement.
- The practice expenses and income are distributed in accordance with methods previously determined by members of the group.

In the case of faculty practice plans associated with hospitals that have approved medical residency programs for which plan physicians perform specialty and professional services, both within and outside the faculty practice, this definition applies only to those services that are furnished to patients of the faculty practice plan.

''Group practice'' as defined in section 1877(h)(4)(A), as it reads under OBRA '93, is discussed in section II.D.1.c.4. of this preamble.

a. Threshold for ''Substantially All''

Comment: A few commenters suggested that the threshold for what is ''substantially all'' of the services of physician members should be lowered from 85 percent to 75 percent because rural group practices would have difficulty in meeting the higher percentage. The same commenters noted that, if the threshold for group practices is not lowered, there should be a special threshold for rural group practices that may not be able to meet the 85 percent standard.

Response: The comments we received on the proposed rule have identified group practices that have partners, full and part-time physician employees, and physician contractors, who may also be either full- or part-time. All configurations of physicians must be

able to show that the statutory requirements are met and, specifically, that substantially all of the services of the members are furnished through the group. (We discuss in a later comment which physicians qualify as ''members'' of a group practice.) As we have mentioned previously in this preamble, it is not our intention to unnecessarily impede associations of physicians from qualifying as a group practice, and we recognize that groups that have part-time physicians may have a more difficult time qualifying than groups that have all full-time physicians.

We agree that the 85 percent criterion should be reduced to 75 percent, and we have made that change in the definition of group practice (§ 411.351). Before deciding to make this change, we considered the implications for group practices that have part-time and contractual physicians and the possibility of establishing separate standards for rural and urban locations and the changes that will be made by the OBRA '93 provision on January 1, 1995. (Beginning on January 1, 1995, members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice.) We accept the point of view that a standard higher than 75 percent would be difficult for many rural group practices to meet. That is because the scarcity of physicians in rural areas generally imposes varying responsibilities that cause these physicians to devote less time to a group practice than might be the case in other areas. In order to be consistent and to eliminate whatever administrative confusion might result from different standards for rural and urban areas, we are adopting the 75 percent standard for all areas.

Comment: One commenter indicated that group practices should be allowed to select the methodology for determining the 85 percent threshold; that is, 85 percent of total physician time, or 85 percent of total group income (calculated on the basis of allowed charges, etc.), or 85 percent of all physicians' services delivered—whatever method they prefer to use and are able to document.

Another commenter recommended that the Medicare allowed charges or fee schedule amounts be used as the measurement criterion for the following reasons: (1) By using such a measure, the necessary data would be readily available to Medicare carriers in the Medicare databases; (2) these measures would not impose any new record keeping obligations on physicians and group practices; and (3) if alternative measures, such as time, patients, service, or total revenue were used, physicians and group practices would be subjected to additional burdensome record keeping requirements.

A third commenter suggested that the following conditions indicate that the criteria are met: All Medicare allowed charges or fee schedule amounts for the services furnished by all physician members of the group are furnished through the group, and billed in the name of or under a number or numbers assigned to the group practice, and the amounts received are treated as receipts of the group.

Finally, another commenter recommended that we consider (1) excluding from the formula any part-time physician who does not refer work to the laboratory for Medicare patients, and (2) revising the current 85 percent formula to provide that, so long as 85 percent of Medicare laboratory work is attributed to full-time physicians (a full-time physician being a person who bills at least 85 percent of his or her services through the group), the group practice would then be able to meet the exception.

Response: As noted, we proposed that, to meet the ''substantially all'' criterion, a group practice would have to be able to show that at least 85 percent of the aggregate patient care services furnished by all physician members of the group practice are furnished through the group practice. In addition, as stated in section 1877(h)(4)(B), these services must be billed in the name of the group, and receipts for the services must be treated as receipts of the group. After carefully considering the language of the statute and these comments, we decided to adopt the following approach:

We are continuing to provide that to meet the ''substantially all'' criterion, in the aggregate, a specific percentage of patient care services furnished by all physician members must be furnished through the group practice. As we noted in an earlier response, we are changing the percentage from 85 percent to 75 percent. The comments have revealed that there is confusion about what constitutes ''patient care services'' and how to measure them. To remedy this, we are clarifying in the regulation that patient care services include any tasks performed by a group practice member that address the medical needs of specific patients, whether or not they involve direct patient encounters. As a result, patient care services can involve the work of pathologists and radiologists who do not directly treat patients or a physician's time spent consulting with another physician when the patient is not present or time spent reviewing laboratory tests.

We are also clarifying that a practice must measure patient care services by calculating the total patient care time each member spends on patient care services. We believe that this method of measuring services is an equitable one that will capture most accurately a group practice member's commitment to providing services through the practice. For example, if a member furnishes only a few services through the practice during the course of a week, but these services are surgical procedures that consume most of the physician's time that week, this fact will be reflected in the calculations.

As to the first comment, we do not believe that leaving this matter entirely to the discretion of each group practice would be feasible. It is our goal to accomplish fairness and evenhandedness across group practices by establishing a consistent and uniform approach. Leaving the matter to the discretion of each group practice would also put an additional burden on the Medicare carriers. The carriers could very well be involved in audits of group practices in the future. If we adopted the commenter's suggestion, a carrier would, on the occasion of each audit, first have to determine whether a particular method employed by a group practice is appropriate before determining whether the standard is met. Thus, we are clarifying that, to meet the substantially all criteria, 75 percent of total patient care services (measured as patient care time) of group practice physicians must be provided through the group.

It is not clear to us how using a method employing Medicare allowed charges or physician fee schedule amounts would satisfy the statutory requirements. The carriers would have this information, as the commenter stated, but section 1877(h)(4) does not say that only substantially all of a group practice's Medicare business be considered. The reference is to ''* * * substantially all the services of the physicians who are members * * *.'' Accordingly, we believe that all services, both Medicare and non-Medicare, must be considered.

Here is an example of how our uniform total patient care time approach would work:

Ten physicians deliver services through a group practice. Eight of them devote 100 per cent of their patient care time to the group practice. One devotes 80 percent, and one 10 percent. This can be illustrated as follows:

8 physicians at 100% each =	800%	
1 physician at 80% =	80%	
1 physician at 10% =	10%	
	890%	divided by 10 = 89%

Thus, in this example, 89 percent of the total of the time spent by these physicians is devoted to services billable by the group practice. The issues of group practice billing numbers and part-time physicians are discussed below.

Comment: One commenter suggested that the calculations for substantially all services be made, at the election of the practice group, with respect to either the previous fiscal year of the practice group or the previous 12-month period, which is the approach used by the safe harbor regulations. The commenter believed that a 12-month period is appropriate for this purpose in order to avoid short term fluctuations that might otherwise distort the determination.

Response: We agree that a 12-month period is appropriate for use in determining compliance with the ''substantially all'' criterion. We will allow a group practice (as defined in section 1877(h)(4)) to elect whether to use the calendar year, its fiscal year, or the immediately preceding 12-month period to determine whether it complies with the standard. Furthermore, we will allow any new group practice (one in which the physicians have only recently begun to practice together) or any other group practice that has been unable in the past to meet the requirements of section 1877(h)(4) (including the ''substantially all'' criterion) to initially look forward 12-months, as described below, to determine compliance with the standard. These groups would also be able to elect whether to use the calendar year, fiscal year, or the next 12-months. Finally, once any group has chosen whether to use its fiscal year, the calendar year, or another 12-month period, the group practice must adhere to this choice.

In new 411.360, each group practice must submit to its carrier an initial attestation that the group has met the ''substantially all'' criterion (75 percent of patient care time) in the 12-month period it has chosen. New group practices or other groups that wish to initially use future months to meet the ''substantially all'' criterion must attest that they plan to meet the criterion within whatever upcoming 12-month period they have chosen and will take measures to ensure the standard is met. After this 12-month period is over, the group must attest that it did meet the standard during that period.

The attestation must contain a statement that the information furnished in the attestation is true and accurate and must be signed by a representative for the group. It must be mailed to the carrier within 90 days after the effective date of this final rule, that is, 120 days after the date of publication of this rule in the **Federal Register**. We are requiring this initial attestation so the carriers will be able to determine whether payment for laboratory services should be continued. After their initial attestation (whether it is retroactive or prospective), group practices must submit updated attestations to the carrier each year at the end of the period they have chosen to use to measure this standard.

If a group practice using an initial prospective period does not meet the ''substantially all'' criterion at the end of its chosen 12-month period, the group would not qualify as a group practice. As such, an overpayment could exist from the beginning of the period in which the group has claimed that it would meet the ''substantially all'' standard.

This approach does have paperwork burden implications for group practices. However, we do not believe that the burden is significant. It should be a relatively easy task for most group practice physicians to assess the amount of their patient care time that is spent on services that can be billed in the name of the group.

b. Member of a Group

Comment: Several commenters indicated that we should define more precisely what is meant by a ''member'' of a group practice because the ''substantially all'' criteria apply to physicians who are ''members'' of a group practice. For example, one commenter suggested that for part-time members of a group practice, only that percentage of time/services/income devoted by the member to the group should be assigned to the group for the purpose of calculating the total time/services/income of the group.

Several commenters indicated that the term ''member'' of the group practice should have a restrictive definition, such as one that is limited to principals of the practice, for example, shareholders, partners, or officers.

Another commenter indicated that the term ''member'' can be broadly interpreted to include all physician employees or even independent contractor physicians of the group practice, and that how the term is defined can have significant impact. Yet another commenter recommended that the term ''member'' be defined to include physician owners as well as full- and part-time employed physicians.

One commenter recommended that the definition exclude any physician who is not a shareholder, partner, or employee of the group, or an independent contractor providing more than a certain number of hours of service per week (for example, 20 hours) for the group. The commenter stated that such a rule is supported by common sense, as it is doubtful that physicians who furnish services on a sporadic basis would consider themselves to be members of a group or qualify for the various benefits associated with being a member of the group.

On the other hand, another commenter stated that, if the term ''member'' is given a restrictive definition, limited to principals of the group practice, the practice will be able to circumvent the 85 percent aggregate services requirement simply by ensuring that no physician who provides substantial services outside the group becomes a principal of the group. The commenter believed that limiting the definition, however, might restrict the numbers of physicians who may supervise laboratory testing under the in-office ancillary services exception because it applies to only services furnished by or supervised by physicians who are ''members'' of the same group practice. The commenter also suggested that it might affect where that testing may take place. Under section 1877(b)(2)(A)(ii), testing may be done in a building in which the referring physician (or another physician member of the group practice) has a practice or in another building which is used for the centralized provision of the group's clinical laboratory services. Particularly in multi-site group practices, the referring physicians could be physician-employees or independent contractors who would not be ''members.'' Thus, their laboratory tests would have to be performed in a building in which a member personally supervises the laboratory services. This, however, would not seriously impede the group practice, in this commenter's view, as most group practices could readily set themselves up in a manner that allows for at least one principal to be available for supervision. This commenter further stated that a broader definition of the term ''member'' that includes all physician employees and/or

independent contractors leads to different results. That is, it might make it more difficult for the group practice to satisfy the 85 percent aggregate services requirement in the definition, depending on the number of part-time employees and contractors. However, it would allow for almost any associated physician to make referrals and supervise the performance of laboratory services.

Response: As evidenced by the range of comments we received concerning this group member issue, whatever approach we select may not address all of the concerns raised by the commenters. Essentially, we agree that the issue of who qualifies as a ''member'' of a group practice raises a number of complex questions. As we understand it, group practices typically have partners, full-time physician employees, part-time physician employees, and physician contractors.

We take the position that all of these physicians can be members of a group for purposes of the group practice provisions of section 1877. We consider physician partners and full-time and part-time physician employees and contract physicians to be members during the time they furnish services to patients of the group practice that are provided through the group and are billed in the name of the group. Thus, their services would be considered in determining whether the group practice as a whole meets the requirement that substantially all of the services of physician members be furnished through the group.

Examples are as follows:

• A group practice consists of two physician partners, five full-time physician employees, two part-time physician employees, and a contractor physician who spends one morning a week at the group practice delivering specialty services. The two partners and the full-time employees practice only through the group. The two part-time employees devote 50 percent of their time to the group, and the contractor physician spends 10 percent of his or her time with the group.

7 physicians at 100% =.	700%	
2 physicians at 50% =.	100%	
1 physician at 10% =.	10%	
	810%	divided by 10 = 81%

• In another group practice, two physician partners spend 100 percent of their patient care hours through the group. Five part-time physician employees spend 70 percent each, and two other part-time physician employees spend 25 percent of their time at the group practice. A contractor physician devotes 10 percent.

2 physicians at 100% =.	200%	
5 physicians at 70% =.	350%	
2 physicians at 25% =.	50%	
1 physician at 10% =.	10%	
	610%	divided by 10 = 61%

In these examples, using 75 percent as the threshold, the first group practice would qualify, but the second would not.

On balance, we believe this approach is the most appropriate and is neither overly restrictive nor overly permissive. It will eliminate problems that might arise for many group practices that employ physicians or contract for the services of physician specialists on a part-time basis. Because this approach is not overly restrictive, we do not believe it will obstruct rural group practices. On the other hand, as demonstrated in the above example, the inclusion of part-time physicians may cause some group practices to fail to meet the 75 percent aggregate requirement.

To clarify our position about this issue, we have included the following definition under section 411.351 (''Definitions''):

Members of the group means physician partners and full-time and part-time physician employees and physician contractors during the time they furnish services to patients of the group practice that are furnished through the group and are billed in the name of the group.

c. Individual Billing by a Group Practice Physician

Comment: A few commenters indicated that some group practices permit the physicians of the group to bill Medicare under their unique physician identification number. Under the proposed rule, they do not meet the definition of a group practice because services furnished by the group physicians are not billed in the name of the group. The commenters requested an exception for a few group practices that actually practice medicine as a group but do not qualify because of this element of the new definition of group practice.

One commenter indicated that many group practices have made a decision to have each physician bill independently and reassign benefits to the group rather than for services to be billed under the group's provider number. This decision is based on the desire of some physicians within the group to be nonparticipating physicians but only for the services billed by the group as group services. (As nonparticipating physicians, they can bill the beneficiary directly and charge for the part of the bill that is more than the Medicare approved amount, with certain limitations.) According to the commenter, the physicians would agree to bill under a group provider number except for an informal, nonregulatory position that all physician members of a group practice must make a joint decision to be either participating or nonparticipating physicians. The commenter recommended that the final rule clarify that billing in the name of the group allows for physician members of a group to make individual choices about participating or not participating in Medicare. It was suggested that such a decision could be made at a ''department level'' within the group practice by differentiating between specialty categories.

Response: The definition of a group practice set forth in section 1877(h)(4)(A) requires that substantially all of the services of physicians who are members of the group be provided through the group and be billed in the name of the group. (Beginning January 1, 1995, services must be billed under a billing number assigned to the group.) Under this language, an organization whose individual physicians bill in their own name does not constitute a group practice. Additionally, the services of a physician who does not bill in the group's name cannot be counted in determining whether the group practice satisfies the substantially all criteria.

We recognize that, under the in-office ancillary services exception found in section 1877(b)(2)(B), the physician who performs or supervises the performance of the services may also bill for those services. As mentioned above, however, when a physician bills in this manner, he or she is doing so as a solo practitioner and not as a member of a group practice.

Finally, when a bill is submitted in the name of the group on an assignment-related basis, it is the group that accepts assignment. A Medicare participation agreement under section 1842(h)(1) is an agreement to accept assignment in all cases. Therefore, any participation agreement with respect to services

furnished by a group must be entered into by the group and must apply to all services that the physicians furnish as members of the group.

d. Structure of a Group Practice

Comment: One commenter stated that the definition of ''group practice'' applies not only to professional corporations and other single entities but also to ''similar associations.'' The commenter believed that, when a group practice is organized into two separate entities that are organizationally interrelated through common ownership, administration, or similar substantial and ongoing connections (more than merely their joint ownership of a clinical laboratory), the two entities together should qualify as a similar association under the statute, thus allowing the two entities to satisfy the group practice criteria in the aggregate.

The commenter believed that if such entities are not aggregated for purposes of the group practice definition, then the primary care entity that has the laboratory must qualify separately as a group practice. Further, under the group practice definition, as set forth in the proposed rule, this may be impossible. The commenter described a situation involving a primary care entity and a specialty care entity. These two entities share certain office space, facilities, equipment, and personnel that physicians practicing in both entities jointly use. Thus, as stated by the commenter, there are two group practices sharing a laboratory facility. The commenter believed that each physician member of these entities does furnish the full range of his or her services through the joint use of space, facilities, equipment, and personnel, and the entities allocate the costs of this use on a formulaic basis. The commenter believed the organizational structure described in this situation should meet the conditions in the statute. The commenter pointed out that the preamble to the proposed rule states that each member of the group must individually furnish substantially the full range of services he or she routinely furnishes *through the group practice*. The commenter argued that this language is contradictory to the statute, which requires that each physician who is a member furnish the full range of services *through the joint use of shared space*, etc.—not furnish the full range through the group practice. The commenter suggested that the final rule state the actual requirements.

Response: It appears to us that what the commenter is describing is a situation in which two interrelated group practices share a laboratory. The physicians' services exception under section 1877(b)(1) allows members of the same group practice to refer Medicare patients to each other for clinical laboratory services, as long as one of the physicians either personally performs the services or personally supervises the provision of the services. Thus, section 1877(b)(1) clearly contemplates physicians *within the same* group practice, but not physicians in different group practices. The in-office ancillary exception in section 1877(b)(2) allows members of the same group practice to refer to each other as long as the physician providing or supervising the services meets the tests in section 1877(b)(2) (A) and (B) for personal performance or direct supervision, location, and billing.

To qualify for the in-office ancillary services exception, an organization of physicians must meet the definition of a ''group practice'' under section 1877(h)(4). Under the definition, a group practice ''means a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association.'' We agree that, in including a ''similar association'' in the list, the Congress has provided some flexibility for different kinds of entities to qualify as group practices. Nonetheless, we also believe that the statutory definition clearly contemplates only single legal entities. We do not view two independent group practices as a single practice, just because they are organizationally interrelated through common ownership or other substantial and ongoing connections.

We believe that the statute would have explicitly allowed for a ''common ownership'' or ''substantial connection'' configuration as part of the group practice definition had the Congress intended to include it. Also, it appears to us that using the premise of common ownership or substantial connection to combine individuals and entities could lead to far-reaching exceptions to the referral prohibition that we do not believe the Congress ever intended. For example, two solo practitioners could state that they are interrelated through shared administrative services and their common ownership of a shared laboratory, thus qualifying them as a similar association.

As we explain throughout this preamble, we do not believe that a clinical laboratory that is shared by associations of physicians who do not meet the definition of a single group practice will generally qualify for the in-office ancillary services exception. However, each individual physician in these groups might qualify separately for the exception by meeting the requirements in section 1877(b)(2). That is, the physician must personally furnish the services or directly supervise the individual(s) that are furnishing the services. Further, the services must be furnished in a building in which the referring physician furnishes physicians' services unrelated to clinical laboratory services, and the services must be billed by the physician or an entity wholly owned by the physician.

Comment: One commenter indicated that we should address the issue of group practices that may include more than one legal entity as long as the entities either are in parent-subsidiary relationships or are under common ownership and control. The commenter stated that the proposed definition of group practice requires an entity to be legally organized, and gives multiple examples of the types of legal entities typically used in group practices. The commenter believed the definition is silent on the question of whether a group practice may have more than one such legal entity under a common umbrella. For example, a ''parent'' professional corporation or partnership might own subsidiary entities for real estate and/or equipment ownership or for billing or ancillary services. Alternatively, rather than having a parent/subsidiary relationship, these same types of separate entities might operate jointly under the common ownership and control of a core group of physicians. These separate structures have been highly desirable for reasons related to taxation, benefits, liability, debt service capacity, etc.

Response: This commenter was concerned about groups of physicians who furnish services through a ''group practice'' that is composed of several legal entities. The commenter believed that such a group practice should be able to take advantage of the in-office ancillary services exception as long as the entities are in either parent-subsidiary relationships or are under common ownership and control. The commenter specifically mentioned examples in which a professional corporation might own subsidiaries for providing equipment, for billing, or for ancillary services.

The definition of ''group practice'' in section 1877(h)(4)(A) means a group of 2 or more physicians, legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association. As we have said elsewhere in this preamble, we believe that the statute contemplates a group

practice that is composed of one single group of physicians who are organized into one legal entity. In short, we do not believe that a group practice can consist of two or more groups of physicians, each organized as separate legal entities.

However, we do not believe the statute precludes a single group practice (that is, one single group of physicians) from owning other legal entities for the purpose of providing services to the group practice. Thus, a group practice could wholly own a separately incorporated laboratory facility which provides laboratory services to group practice or other patients. However, because the group practice physicians have an ownership interest in the laboratory, they could be prohibited from referring to the laboratory, unless an exception applies.

The physicians could qualify for the in-office ancillary services exception, provided they meet the requirements for supervision, location, and billing. This exception does not appear to dictate any particular ownership arrangements between group practice physicians and the laboratory in which the services are provided. In fact, the billing requirement in section 1877(b)(2)(B) allows the services to be billed by the referring physician, the group practice, or an entity wholly owned by the group practice. The exception appears to anticipate that a ''group practice,'' as defined in section 1877(h)(4), may wholly own separate legal entities for billing or for providing ancillary services.

e. Corporate Practice of Medicine

Comment: Two commenters indicated that there are legitimate physician group practice structures and relationships that may not satisfy the definition of a group practice as set forth in the proposed rule. A specific concern is with group practice organizations affiliated with hospitals that are organized in compliance with State corporate practice of medicine statutes.

In States that have these statutes, according to the commenters, only a validly-organized professional corporation or professional association can enter into employment arrangements with physicians.

One of the commenters presented an example of a group practice that is organized as a nonprofit hospital affiliated corporation that owns a clinical laboratory. The nonprofit hospital-affiliated corporation will be unable to employ the physicians; that is, a separate professional corporation must be established to employ the physicians in accordance with applicable State law. Typically, this commenter claimed, nonprofit corporations will not qualify as the appropriate vehicle for a for-profit professional corporation or association.

The commenters believed that entities such as those described above (joint not for profit/for profit structures) that meet certain specific standards should qualify under the ''similar association'' language of the group practice definition. They believed that, so long as all other requirements established by the Secretary relating to appropriate standards for group practices (including the performance of services, billing practices, location of facilities, and income distribution provisions) are met, these entities do not pose a threat of abuse to the Medicare program and, as a result, they should be considered as a single group practice under the definition. To ensure that only appropriate entities qualify, one commenter suggested that (1) the separate professional corporation be organized for the sole purpose of providing medical services to the nonprofit corporation/group practice and be obligated to furnish those services exclusively to the nonprofit corporation, and (2) that the nonprofit corporation perform all other services associated with a group practice (including laboratory, billing, etc.) and employ all nonphysician staff.

Response: We believe the commenters are asking that we regard a joint structure, such as a nonprofit hospital-affiliated corporation linked with a professional corporation or association, as one group practice. This designation would allow the physicians in the professional corporation or association to refer to the nonprofit corporation's laboratory under the physicians' services or in-office ancillary services exceptions in section 1877(b).

In order to meet the definition of a group practice, there must be one identifiable legal entity. As we understand it, the clinical laboratory is owned by a nonprofit hospital-affiliated corporation but, because of the corporate practice of medicine requirements, that nonprofit corporation is unable to directly employ the physicians. As a result, the physicians are members of a separate professional corporation or association. The hospital-affiliated corporation and the professional corporation or association are separate legal entities that cannot qualify as one group practice. Also, because the hospital-affiliated corporation cannot directly employ the physicians, the exception in section 1877(e)(2) does not apply. (This exception allows referrals by a physician when there is a compensation arrangement between an entity and a physician for the employment of the physician.)

We see one possible exception for a nonprofit corporation that is affiliated with physicians who perform certain physician services. Under section 1877(e)(3), as amended by OBRA '93, there is an exception from the prohibition on physician referrals in the case of a personal service arrangement involving remuneration from an entity to a physician, or to an immediate family member of a physician, providing—

- The arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement;
- The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity;
- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;
- The term of the arrangement is for at least 1 year;
- The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;
- The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law; and
- The arrangement meets any other requirements the Secretary imposes by regulation to protect against Medicare program or patient abuse.

If the nonprofit corporation (that owns the laboratory) and the professional corporation or association (that has physician investors) have such an arrangement, the physicians would not be prohibited from referring laboratory testing to the nonprofit corporation's laboratory.

f. Not-For-Profit Corporations

Comment: One commenter asked about the provision that permits group practices to be legally organized as not-for-profit corporations. The proposed rule defines a ''group practice'' as ''a group of two or more physicians legally organized as * * * a not-for-profit corporation * * *.'' The commenter, however, stated that not all group practices organized as not-for-profit groups have physicians as their original incorporators or corporate members, nor

is this required by State law. As an example, the commenter stated that tax-exempt hospitals often have affiliated group practices, and the group practice's operating entity (to which the commenter referred as a ''physician-directed clinic'') might be a not-for-profit corporation separate from the tax-exempt hospital entity that employs the physicians. This arrangement does not present a potential for abuse, in the commenter's view, although it is unclear whether a not-for-profit physician-directed clinic organization affiliated with a not-for-profit hospital in this manner meets the definition of a group practice. Therefore, the commenter recommended that the final regulation recognize the arrangements.

Response: As we understand the commenter's example, a tax-exempt hospital employs physicians who are part of an affiliated not-for-profit physician-directed clinic that was originally organized by the hospital. (Under Medicare, a physician-directed clinic is one in which (1) a physician (or a number of physicians) is present to perform medical (rather than administrative) services at all times the clinic is open; (2) each patient is under the care of a clinic physician; and (3) the nonphysician services are under medical supervision. (See Medicare Carriers Manual, section 2050.4.)) Further, we understand the commenter to be making the following suggestions:

- That an entity attempting to qualify as a group practice need not have been organized (or incorporated) by physicians; that is, as long as the entity is one in which two or more physicians have been brought together as a group practice, it does not matter that the initial organizing was done by nonphysicians.
- That an entity that, in fact, is a physician-directed clinic, organized by an affiliated hospital, be permitted to qualify as a group practice.

As to the first suggestion, the commenter referred to only the regulations, but the definition of ''group practice'' at section 1877(h)(4) also requires that there be ''two or more physicians legally organized'' as a not-for-profit corporation or as one of several other specified associations. Because the statute is silent about who must actually legally organize the association or operate or control it, we believe that any individuals or entities can assume these tasks, as long as the group practice meets all of the other specific requirements in section 1877(h)(4). Thus, if a clinic (or other facility) is legally organized to include two or more physicians and provides the services of physicians, it is a group practice, even if it is established, operated, and controlled by a nonphysician group or corporation. This would be so regardless of who employs the physicians (in the scenario presented by the commenter, the clinic physicians were employed by the hospital that established the clinic).

g. Individual Pathology Services

Comment: One commenter suggested that the proposed regulations may preclude arrangements under which a group practice retains the services of an independent pathologist to direct the group's laboratory or otherwise assist in improving the quality of laboratory services available. The commenter wrote that the group practice may not be able to satisfy the definition of a group practice laboratory for purposes of section 1877(b)(2) if it retains the services of an independent pathologist who is not considered a member of the group, but who provides medical direction to the laboratory. Second, according to the commenter, an independent pathologist affiliated with a reference laboratory may be unwilling to provide consulting services to a group practice laboratory unless the consulting arrangement is specifically excepted by the regulations. Therefore, the commenter requested that the final regulations provide that (1) a pathologist retained by a group practice on a regular, part-time basis to direct, supervise, and otherwise assist in the performance of laboratory services be considered to be a member of the group practice; and (2) the services of a pathologist serving as a laboratory consultant be included within the category of exceptions set forth in proposed Section 411.359(e)(1)(i) (that is, service arrangements with nonhospital entities).

Another commenter requested that we develop an additional exception relating to compensation arrangements involving the provision of consulting services, as opposed to the furnishing of actual testing services. The commenter suggested that the arrangement would have to be: in writing, consistent with fair market value for the consulting services provided, and not conditioned on referral of laboratory services from one party to the other or otherwise related to the volume or value of referrals for laboratory services.

Response: First, part-time or contract physicians, including independent pathologists, may be considered members of a group practice if they meet the conditions in the ''member'' definition in § 411.351. As indicated by the commenter, a group practice can hire a pathologist to direct, supervise, or otherwise assist in performing laboratory tests. We agree that this is an important point because the most significant advantage of a practice meeting the group practice definition is that it qualifies the group for the in-office ancillary services exception in section 1877(b)(2). This exception applies if the referring physician or *another member* of the same group practice either performs or directly supervises the performance of the laboratory services. A group practice would not be able to use the section 1877(b)(2) in-office exception if it is a group practice member who is referring patients to the group's laboratory, but it is a nonmember pathologist who is performing or supervising the laboratory services.

The second concern of the first commenter involves an independent pathologist, who is somehow ''affiliated'' with an outside laboratory, who might be unwilling to provide consultation services to a group practice laboratory unless the consulting arrangement is specifically excepted from the prohibition by the regulations. Following is our analysis of such a situation.

First, the group practice laboratory is itself a laboratory entity that is compensating a pathologist (physician) for certain services the physician is providing and that relate to the group's laboratory services. We believe the pathologist could refer to the group practice laboratory if this arrangement fits within the exception in section 1877(e)(3). Section 1877(e)(3) excepts from the term ''compensation arrangement'' payments *from an entity to a physician* for personal services provided by the physician under an arrangement. The arrangement must meet certain criteria (for example, the arrangement must list the specific services in writing, be signed, be reasonable and necessary, and compensation must be for fair market value).

Section 1877(e)(3) does not appear to differentiate between physicians receiving compensation on the basis of whether they are independent contractors who also service other outside laboratories or whether they are employees or owners of outside laboratories.

The group practice could also be regarded as a group of physicians who may be purchasing services from an outside laboratory (if the pathologist is employed by or owns the outside laboratory). If this is the case, the compensation could instead be excepted under section 1877(e)(8). This provision excepts payments *made by a physician*

to an entity as compensation for items or services other than clinical laboratory services if they are furnished at a price that is consistent with fair market value.

If the pathologist is considered a member of the group practice and makes referrals to the outside laboratory, whether the referrals would be prohibited depends upon the nature of the pathologist's relationship with the laboratory. The referrals might not be prohibited if the pathologist is the employee of the outside laboratory. In that situation, the payment the pathologist receives from the outside laboratory would not be ''compensation'' under section 1877(e)(2), which exempts any amount paid by an employer to a physician who has a bona fide employment relationship with the entity for the provision of services if certain standards are met.

If the pathologist is independent but contracts with the outside laboratory, the compensation that flows from the outside laboratory to the pathologist could be excepted under section 1877(e)(3). This provision excepts remuneration from an entity under a personal service arrangement if certain standards are met.

If the pathologist owns the outside laboratory though, his or her referrals would be prohibited. That is because the pathologist would be referring to a laboratory in which he or she has an ownership interest (the section 1877(e) provisions except only compensation arrangements). Finally, if the pathologist is a member of the group practice, none of the group practice members can refer to the laboratory that is owned by the pathologist. That is because, in Section 431.351 of the proposed rule, we defined ''referring physician'' as a physician (or group practice) who makes a referral. Thus, any referral by one group practice member is imputed to the entire group practice.

7. Immediate Family

Under the proposed rule (§ 411.351) an ''immediate family member'' of a physician means husband or wife; natural or adoptive parent; child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

Comment: Two commenters recommended that we adopt what they believed to be a more manageable definition of immediate family member. They recommended eliminating, at the very least, the references to grandparents, grandchildren, and assorted in-laws.

One of the two commenters recommended that the definition include ''natural or adoptive parent, child or sibling'' and exclude the remainder of the identified relatives. In this commenter's view, the definition of immediate family reaches beyond what is intended by the statute.

Response: As we stated in the proposed rule, our proposed definition is a longstanding definition used (in § 411.12) by the Medicare program to implement section 1862(a)(11), which excludes from Medicare coverage services furnished by an immediate relative. We also explained that, in our view, the definition encompasses the range of relatives who could be in a position to influence the pattern of a physician's referrals. These commenters simply stated their opinion that the definition is overreaching, without explaining why.

For these reasons, we are retaining the definition as proposed.

Comment: One commenter suggested that when an allowable clinical laboratory service is performed as part of a medical consultation by a family member of the referring physician, we should not prohibit that referral solely because the consulting physician is related to the referring physician.

Response: Under the definition of referral in section 1877(h)(5)(A), the request by a physician for an item or service covered under Part B, including the request by a physician for a consultation with another physician, and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician, constitutes a ''referral'' by a ''referring physician.'' The first physician has, in sending his patient to the family member, made a referral under the statute.

If the family member performs or supervises the performance of the laboratory test, it is likely that the family member has either an ownership interest in the entity that performed the test and/or is compensated by the entity for supervising or performing the test. As a result, the first physician has referred a patient for laboratory tests to an entity with which his or her immediate family member has an ownership or compensation relationship. If no exceptions apply, this makes the referral a prohibited one. If the consultant family member merely orders the laboratory test from a laboratory in which neither he or she nor the first physician has a financial interest, the referral would not be prohibited.

We also point out that section 1877(h)(5)(C) provides that if a pathologist performs a laboratory test or supervises the performance of a test that is part of a consultation requested by another physician, the furnishing of the test by the pathologist or his or her request that the test be completed (under the pathologist's supervision) is not a referral. In other words, a self-referral by a pathologist as a result of a consultation does not constitute a referral for purposes of section 1877.

Comment: One commenter is a solo practitioner whose office is located in a building owned by herself and six other physicians, one of whom is her husband. In the building, there is an independent laboratory that is owned by the group practice to which her husband belongs. The laboratory was established by the physicians in the building for the practices in the building. The commenter did not think it is right that, because her husband has an ownership interest in the laboratory, her patients should not have access to it.

Response: Unless an exception applies, it appears, on the face of it, that the commenter is correct in stating that her referrals to the independent clinical laboratory would be prohibited. Her relationships with the laboratory appear to be as follows:

- She may have been an investor in the laboratory, because she was one of the ''physicians in the building'' who set the laboratory up ''for the practices in the building.''
- She is the spouse of a member of the group practice that now owns the laboratory.
- She is part owner of the building that houses not only the laboratory, but her solo practice and her husband's group practice as well.

It appears, therefore, that this physician, in addition to being an immediate family member of what may be a partial owner of the laboratory, may also be an investor in the laboratory herself (depending on the nature of her initial involvement in setting up the laboratory and any current financial interest) and may have a compensation arrangement with the laboratory based on rentals she presumably receives as a part owner of the building. We believe, however, that her family relationship generally controls to prohibit her referrals if her husband has an ownership or investment interest in the group practice or its laboratory or if he receives unexcepted forms of compensation from the group practice.

The physician's referrals would not be prohibited on the basis of her husband's ownership interest if the laboratory qualifies as a rural laboratory under

§ 411.356(b)(1). Note that, as discussed elsewhere in the preamble, unless the group practice that owns the laboratory satisfies the definitional requirements, referrals by group practice physicians to the laboratory might also be called into question.

8. Practice

In the proposed rule (411.351), we defined a ''practice'' to mean an office in which the physician, as a matter of routine, sees patients for purposes of diagnosis and treatment and where patient records are kept.

Comment: One commenter indicated that many group practices provide medical services in satellite facilities where only limited medical services are offered and that the medical records of the group practice are kept in a centralized location. Thus, the commenter recommended that we clarify in the final rule that the definition of ''practice'' is not incorporated into the definition of ''group practice.''

Another commenter stated that some physicians maintain a medical practice without being tied to a particular location, such as certain hospital-based physicians and those who treat nursing home patients. These physicians use office space only to receive mail and for other administrative support functions. Such a practice, be it group or individual, does not have an office for purposes of diagnosis and treatment, or even to keep substantial amounts of medical records. The commenter believed this fact is not taken into account in the definition.

Response: We acknowledge that the commenters have raised some legitimate problems with the proposed approach and how difficult it is to determine where someone has a ''practice.'' We are responding to these comments by creating a new, more equitable standard that is not based on the concept of a physician's ''practice'' (and thus eliminate the definition from the rule). We are using the new standard required by OBRA '93, which states that to qualify as a rural provider, substantially all of the clinical laboratory services furnished by the entity must be furnished to individuals residing in the rural area. As part of this standard, we are defining ''substantially all'' as meaning that 75 percent of the individuals to whom services are furnished reside in the rural area. Although the effective date of this provision for rural providers is January 1, 1995, we believe it is reasonable to incorporate it into this final rule.

9. Referral

In the proposed rule (§ 411.351), a ''referral'' means either of the following:

- The request by a physician for, or ordering of, any item or service for which payment may be made under Medicare Part B, including a request for a consultation with another physician other than a pathologist, and any test or procedure ordered by or to be performed by (or under the supervision of) that physician; or
- If a plan of care includes the performance of clinical laboratory testing, the request or establishment of the plan of care by a physician. When a pathologist, in responding to another physician's request for a consultation, furnishes or supervises the furnishing of clinical diagnostic laboratory tests and pathological examination services, the services are not considered to have been furnished on a referral basis.

a. Pathology Referrals

Comment: Two commenters wanted the definition of ''referral'' to be clarified so as to exclude circumstances in which a pathologist providing professional services to one laboratory sends specimens ordered by the attending physician to a second laboratory in which the pathologist has a financial interest.

One commenter indicated that the definition should also exclude circumstances in which a pathologist recommends to an attending physician appropriate follow-up laboratory services.

Response: Under the definition of ''referral'' in section 1877(h)(5), a request by a pathologist for clinical diagnostic laboratory tests and pathology examination services will not be considered a referral if such laboratory services are furnished by (or under the supervision of) the pathologist as a result of a consultation requested by another physician. Thus, if the pathologist described in the first comment either performs or directly supervises the performance of the laboratory testing in the second laboratory, the request for services would not be considered a referral by the pathologist. The answer is different, however, if the pathologist sends laboratory work to a laboratory with which he or she has a financial relationship and the services are not performed by the pathologist or under his or her direct supervision. The services in this situation would be considered to have been furnished as a result of a prohibited referral, unless one of the exceptions applies. Similarly, if the pathologist sends tests to a laboratory with which the first referring physician has a financial relationship, the referral would be prohibited, unless an exception applies. Because we recognize that there are situations in which a physician's request for a consultation with a pathologist could constitute a referral, this final rule revises the proposed definition of ''referral'' by removing the phrase ''other than a pathologist''.

We do not consider a pathologist's recommendation to the attending physician for additional testing to be a referral. That is because it is the attending physician who ultimately decides whether such testing is necessary and whether to order the additional testing and from what laboratory.

b. Plan of Care and End-Stage Renal Disease (ESRD) Patients

Comment: One commenter indicated that the proposed rule is ambiguous with regard to the ''plan of care'' element within the definition of ''referral.'' At one level, the commenter believed, the language is simply unclear in that, with regard to ''a plan of care that includes the performance of clinical laboratory tests,'' it is difficult to understand what is meant by the ''request or the establishment of the plan of care by a physician.'' According to the commenter, this might mean that when a physician establishes a plan of care that entails laboratory testing and the facility or other individual implementing the plan of care orders those tests from a laboratory, the physician shall be considered to have made the laboratory referral. If this interpretation is correct, the commenter believed there are some issues specific to chronic hemodialysis facilities and referrals that require clarification.

The commenter wrote that hemodialysis patients receive three different classes of clinical laboratory tests:

1. Tests ordered on a patient-specific basis on account of particular clinical signs and symptoms and referred by the dialysis facility to an independent or hospital-based clinical laboratory that bills Medicare. These tests pose no interpretive problems, as the physician does, in fact, order each one individually.

2. Routine monthly testing applicable to every patient and for which payment is incorporated into the facility's dialysis composite rate.

3. Testing integral to monitoring the patient during the dialysis treatment itself, performed in the facility and not billed separately.

The commenter pointed out that every time a patient is referred to a facility for chronic renal dialysis, clinical laboratory testing from categories 2 and 3 is required on an ongoing basis as part of the overall care of the patient. If the physician's plan of care for dialysis is deemed to include these tests for purposes of this rule, the commenter believed that the practical result would be to prohibit physicians from making referrals for tests to dialysis facilities in which they have an ownership interest.

A second commenter stated that the ESRD program includes in its composite rate payment methodology most items and services related to the treatment of patients with ESRD, including hematocrit and hemoglobin tests, clotting time tests, routine diagnostic tests, and routine diagnostic laboratory tests. Thus, the commenter pointed out, the determination of whether an item or service is included under the composite rate payment is presumptive and in no way depends on the frequency with which a dialysis patient requires the item or service. The commenter recommended that the final rule, or the preamble to the final rule, explicitly exclude clinical laboratory referrals covered by ESRD from its application.

Response: Section 1877(h)(5)(B) says that ''the request or establishment of a plan of care by a physician which includes the provision of [clinical laboratory services] constitutes a ''referral'' by a ''referring physician.'' The commenter has pointed out that this provision, carried over into the proposed rule, is ambiguous and unclear. The statute could mean (1) that there is a referral when a physician establishes a plan of care or requests that one be established that includes laboratory services or (2) that a request by a physician that includes the provision of laboratory services or the establishment of a plan of care by a physician that includes the provision of laboratory services constitutes a referral. Because the comments reveal that this provision has caused confusion, we have decided to adopt the latter interpretation and have incorporated it into the regulation.

We also agree that it is not clear what technically constitutes a ''plan of care.'' We believe that any time a physician orders any item, service, or treatment for a patient, that order is pursuant to a plan of care. If a plan of care entails laboratory testing and the facility or other individual implementing the plan orders those tests from a laboratory, the physician who established the plan of care is considered to have made the laboratory referral. In addition, as we mentioned in a previous response, the prohibition could also apply if the individual implementing some or all of the plan of care is a consulting physician. We agree, however, that, under certain circumstances, this may cause problems when those laboratory tests are included in the ESRD composite rate. Thus, as we discuss below, we are including those laboratory tests that are paid under the ESRD composite rate as part of a new exception. We agree that the application of the composite rate constitutes a barrier to either Medicare program or patient abuse because the Medicare program will pay only a set amount to the facilities irrespective of the number and frequency of laboratory tests that are ordered.

c. Consultation Referrals

Comment: A few commenters believed that it was unnecessary for us to include in the preamble the discussion about consultations (57 FR 8595) and the responsibility of a consulting physician to not engage in a cross-referral arrangement. They believed there is no corresponding statutory or regulatory provision and that, except for a small number of truly ''bad apples'' practicing medicine, physicians have not and will not engage in the complicated and tortuous process of directing referrals.

One commenter was concerned that the proposed rule suggests that physicians who refer to consultants have some obligation to tie the consultant's hands when it comes to which clinical laboratories the consultant can use. The commenter believed such an obligation runs afoul of the principle of medical ethics that requires a physician to refer patients to the entity that furnishes the most efficacious service, regardless of other considerations. The commenter indicated that, in a managed care setting, it may be impossible for the attending physician to even know who the consulting physician is, much less be in a position to dictate which laboratory is selected. In sum, this commenter believed that it will be difficult in practice for physicians to determine where the prohibition ends.

Response: We do not agree with these commenters. In response to the first comment, the discussion in the proposed rule was based on the statute at section 1877(g)(4). This provision says that ''any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of [section 1877], shall be subject to a civil money penalty * * *.''

Because the provision applies to physicians who make referrals and to ''other entities,'' we believe that it can apply to consulting physicians who help a physician indirectly make prohibited referrals. In the preamble of the proposed rule (57 FR 8595) we stated that, if a consulting physician deems it necessary to order clinical laboratory services, those services may not be ordered from a laboratory in which the referring physician has a financial interest. We included this explanation to give the reader an example of the kinds of referrals that are prohibited under the statutory definition of ''referral.'' Under section 1877(h)(5)(A), a request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by or performed under the supervision of that other physician) constitutes a referral. Thus, it is necessary for the consulting physician to be aware of any financial relationships the referring physician may have with a laboratory, in order for the referral not to be prohibited. Finally, the consulting physician is also obligated not to refer laboratory testing to an entity with which he or she has a financial relationship, unless an exception applies.

Concerning services furnished in a managed care setting, section 1877(b)(3) provides a general exception for services provided to patients enrolled in the prepaid health plans listed in that provision and in the regulations at § 411.355(c).

d. Statutory Authority

Comment: One commenter noted that the statutory definition of referral encompasses requests for any item or service for which payment may be made under Medicare Part B, but the prohibition contained in the statute is aimed at referrals for clinical laboratory services and not other referrals. Thus, in the commenter's view, the statute makes the rule somewhat confusing. That is, the behavior that the statute seeks to restrict, referrals for clinical laboratory services, is narrower in scope than the behavior of ''referring'' itself. Therefore, the commenter suggested that the final rule clarify that the prohibited behavior is related to clinical laboratory services.

Response: We agree that the definition of ''referral'' under the statute at section 1877(h)(5) is broad. In section 1877(h)(5)(A), for physicians' services, it covers a physician's request for any item or service covered under Part B of

Medicare. For other items, section 1877(h)(5)(B) covers a physician's request or establishment of a plan of care that includes furnishing clinical laboratory services. However, section 1877(a)(1)(A) specifically narrows the scope of section 1877 by describing the subset of referrals that are prohibited. Physicians were originally prohibited from making referrals to an entity for the purpose of providing clinical laboratory services. As of January 1, 1995, physicians are prohibited from making a much broader range of referrals to entities furnishing the other designated health services listed in section 1877(h)(6).

e. Hospitals and Group Practice Laboratory

Comment: One commenter believed that, if there is an ''under arrangement'' agreement between a hospital and a group practice for the group practice to provide laboratory services to hospital patients under section 1861(w)(1), it is the hospital and not the group practice physicians that is making a referral for the purposes of the section 1877 self-referral proscription. The commenter pointed out that, for the most part, as recognized in the proposed regulation, a physician's request for a service is tantamount to a referral to a particular service provider. If services are being furnished to hospital inpatients and outpatients, however, the commenter indicated that it is the hospital's obligation to ensure that the services be performed and to direct that the services be performed by a particular party. Thus, in the commenter's opinion, it is the hospital that is making the referral to the group practice laboratory. Consequently, the commenter recommended clarification of the definition of ''referral'' and ''referring physician'' so that it is clear that a physician's ordering of clinical laboratory services for hospital patients does not constitute a ''referral'' within the meaning of section 1877.

Response: The commenter believed that we should revise the definitions of ''referral'' and ''referring physician'' to make it clear that, in the situation described in the comment, it is the hospital that makes a referral to a group practice laboratory and not the group practice physicians. We disagree with this interpretation. Every referral for clinical laboratory services must originate with a physician, and the general rule in section 1877(a)(1)(A) prohibits a *physician* from making a referral to an entity with which the physician (or an immediate family member) has a financial relationship. A ''referral'' need not even indicate a specific laboratory. Section 1877(h) defines a ''referral'' as any request by a physician for an item or service or the establishment of a plan of care that includes the provision of laboratory services.

We do not believe that the Congress intended to allow physicians to circumvent the referral prohibition by imputing their referrals to an operating entity such as a clinic, hospital, or other institution. We believe that ''referring physicians'' and ''referrals'' involve only individual physicians or groups of physicians who send a Medicare patient or specimen to a laboratory for services.

Although, in our opinion, the general prohibition applies to the situation described by the commenter, there are exceptions within the statute that could apply to allow the group practice physicians to continue to refer.

The commenter has described a situation in which group practice physicians apparently provide patient care services to hospital patients. They refer hospital patients to the group practice's laboratory; the group practice laboratory provides laboratory services for the hospital under arrangements; and Medicare pays the hospital. The referring physicians in this case are referring to a laboratory that receives compensation from the hospital (the hospital buys laboratory services under arrangements). The hospital is also apparently compensating the group physicians for patient care services. The physicians, in addition, are likely to be receiving compensation from the group practice that owns the group practice laboratory and/or they have an ownership interest in the group practice and its laboratory.

We believe that the exception in section 1877(e)(7) could apply to allow referrals based on part of this scenario. This provision says that there is no ''compensation arrangement'' that would trigger the prohibition in section 1877, for arrangements between a hospital and a group practice under which the group practice provides laboratory services but the hospital bills for the services, if certain criteria are met. If the arrangement meets the criteria, the group practice should be able to refer to the hospital's laboratory without violating section 1877. That is because the underlying compensation passing between the hospital (which, in essence, is purchasing services from the group practice laboratory) and the group does not trigger the prohibition.

There is, however, a complicating factor in the commenter's scenario. That is, the group practice physicians are referring to their own group practice laboratory. It is likely that these physicians are receiving compensation from the group practice that owns the laboratory or that they own some portion of the group practice and the laboratory. The compensation or ownership interests involved here would require a separate exception in order to allow the group practice physicians to refer. The services could, for example, be excepted under the in-office ancillary services exception in section 1877(b)(2), which allows a group practice to refer to its own laboratory if certain criteria are met.

In addition, the hospital may be separately compensating the group practice physicians for patient care services, compensation that is independent of the compensation the hospital pays the group to purchase laboratory services. The compensation from the hospital, however, could be excepted under section 1877(e)(2), if there is a bona fide employment relationship between the hospital and the physicians, or section 1877(e)(3) if the hospital is paying the physicians for personal services furnished to the hospital.

10. Referring Physician

We proposed, in § 411.351, to define a ''referring physician'' as ''a physician (or group practice) who makes a referral as defined in this section.''

Comment: One commenter believed that the definition of referral is not necessary because the statute is clear as written.

Response: We incorporated this definition in the rule to make the regulations as complete and clear as possible. Furthermore, this definition interprets the statutory term to include referrals made by an individual physician as well as referrals made by a group practice.

Comment: A commenter raised the issue of a physician who owns or manages a clinic but does not function as a physician by providing care to clinic patients. The physician also owns an interest in a clinical laboratory to which clinic patients or samples are sometimes referred. The commenter believed the physician-owner should not be considered a referring physician within the meaning of the regulation when he or she does not function as a physician. The commenter also believed that, if a clinic owner is only incidentally a physician, that professional degree should play no role in setting his or her legal obligations. In the commenter's view, to include physicians who are mere owners/managers of clinics within the definition of referring physician would be arbitrary and prejudicial to them. The

commenter added that such a physician should be compared to nonphysician clinic owners or managers who are not covered by the statute or its implementing regulations. Clearly, according to the commenter, clinic owners or managers with medical degrees should have the same legal status as nonphysician owners or managers. Thus, the commenter recommended that the final regulation, or its preamble, explicitly exclude from the definition of referring physician, physician-owners who neither practice medicine nor make direct referrals to clinical laboratories.

Response: Section 1877 prohibits referrals by ''physicians'' and does not qualify ''physicians'' to exempt any subset of these individuals. Since section 1877 does not define who is a physician for purposes of that section, the usual Medicare definition of that term applies. ''Physician'' is defined in the statute, at section 1861(r), as a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action (including osteopathic practitioners within the scope of their practice as defined by State law). The definition also includes a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, and a chiropractor. These additional individuals qualify as ''physicians'' only when they are performing within the scope of their license or providing items and services that they are legally authorized to perform within their specialty. The Medicare regulations define ''physicians' services'' at 410.20 as those furnished by one of these individuals who is legally authorized to practice by the State and ''who is acting within the scope of his or her license.'' Arguably then, a physician who owns or manages a clinic but does not provide any of the items or services authorized within the scope of his or her license would not be a ''physician'' for purposes of section 1877. However, if such an individual refers clinic patients to a particular laboratory or attempts to influence a clinic physician to make such referrals, that individual's status changes. That is, he or she has become involved in the care of particular patients and is therefore acting in the role of a physician. As a result, the provisions of section 1877 (including the provision prohibiting circumvention schemes and indirect referrals) would apply.

11. Remuneration

We proposed, in section 411.351, to define ''remuneration'' as ''any payment, discount, forgiveness of debt, or other benefit made directly or indirectly, overtly or covertly, in cash or in kind.''

a. Discounts

Comment: Some commenters supported the concept of including discounts in the definition of remuneration. They indicated that it is not unusual for a physician with substantial Medicare business to obtain a larger discount than a physician who has no Medicare business. Discounts, in the view of these commenters, can therefore influence a physician to use a particular laboratory and, in an extreme case, the prospect of a deeper discount may even induce a physician to order unnecessary tests.

One commenter offered the opinion that the intent of the legislation is clear from the definition of ''compensation arrangement,'' which is defined to include all forms of remuneration, direct or indirect, overt or covert, in cash or in kind.

Another commenter indicated that the existence of a discount arrangement has a strong potential to result in excessive laboratory testing, which contributes to the distressing rise in health care costs in this country.

Some commenters objected to including ''discounts'' in the definition of remuneration because they believed the term ''discounts'' is vague, overbroad, and impossible to define. In their view, the definition would be fraught with unintended adverse consequences. One commenter believed that a compensation arrangement, for the purpose of section 1877, should be created only whenever the following situation occurs: (1) Some remuneration passes from a laboratory to a physician; and (2) the prospect of remuneration gives the physician an incentive to order increased testing.

One commenter indicated that, to a certain extent, physicians receive a lower price than other payers because of the legitimate cost savings associated with physician billing.

Two commenters stated that there is nothing inherently abusive about discounts. One of the commenters believed that what gives the physician an incentive to increase his or her utilization of testing is not the discount; it is his or her ability to mark up the testing and thereby derive a profit from the transaction. The other commenter suggested that discounts be permitted if the laboratory can meet the following conditions:

- The discount is not tied to the referral of Medicare specimens to the laboratory.
- The discount is related to verifiable cost differences in handling specimens that satisfy the conditions for the discount, including cost differences due to such factors as economies of scale, lower billing and collection costs, prompt and regular payment, or reduced bad debt cost.
- The discount is available to anyone who can satisfy the requirements for the discount, for example, type of test or other objective requirement; and
- The discount is not provided to any referring physician. (We assume by this that the commenter meant that discounts a laboratory entity would make to providers of services, such as hospitals, would be permissible under these guidelines.)

Response: As discussed earlier, section 1877(e)(8)(A), as added by OBRA '93, provides that a physician may make payments to a clinical laboratory in exchange for furnishing clinical laboratory services and continue to refer Medicare patients to that laboratory. There is no requirement that the payments meet any particular pricing standards. However, when a laboratory provides a physician with a discount, it may in some cases be providing that physician with a benefit (that is, remuneration) that is separate from the payment that the physician has made to the laboratory to purchase laboratory services. Since we are not interpreting the OBRA '93 provisions in this rule, but merely reiterating them, we have not yet taken a position on how this new provision will affect discounts. We will interpret section 1877(e)(8)(A) and how it applies to discounts in the context of the proposed rule covering all of the designated health services.

In regard to discounts for items and services other than clinical laboratory services, a physician may purchase other things from a clinical laboratory besides clinical laboratory services. Section 1877(e)(8)(B) allows a physician to purchase from any entity items and services, other than laboratory services, as long as they are purchased at fair market value. Section 1877(h)(3) defines fair market value as the value in arm's-length transactions, consistent with the general market value, which would not include discounts. In light of section 1877(e)(8)(B), we are keeping ''discounts'' in the definition of ''remuneration.'' As a result, discounts would remain ''compensation arrangements'' for discounts on items or services such as supplies or personnel or consulting services purchased by a physician from a clinical laboratory or other entity.

Comment: One commenter indicated that providing a discount to physicians

is not necessarily a means of providing them compensation. As an example, the commenter pointed out that in New York, a State that has long had a direct billing law and related regulations, discounts are passed directly on to the patient or insurance carrier. It is a market mechanism that, in the commenter's view, actually works to hold down the cost of health care. The commenter considered discounts a goal to be aimed for, not a practice to be precluded. The commenter indicated that a simple way to help hold down the cost of health care is to follow the direct billing practices established in New York or to exempt those States that already have such laws.

Response: This commenter made a good point. Nonetheless, the Medicare statute generally does not currently authorize us to impose the ''direct billing'' requirement found at section 1877(h)(5)(A) for laboratory services other than those furnished to Medicare patients. As we noted in an earlier response, we will address the discount issue in our proposed rule covering the designated health services.

Comment: A commenter stated that physician groups often contract with HMOs to provide medical care for HMO members and described the following situation: The physician group is paid a predetermined monthly rate per enrollee as payment in full for all outpatient medical services, including laboratory services furnished to covered enrollees. To ensure that the physician group can furnish all necessary services in an efficient and cost effective manner, the physician group typically enters into discount agreements with providers not affiliated with the group to furnish services to the HMO's patients at a discounted rate. These arrangements include laboratory services at a discounted rate.

In the commenter's view, this type of discount arrangement would not pose any risk of Medicare program or patient abuse under the following conditions:

1. The HMO does not bill the Medicare program for any Medicare patient laboratory tests performed by an outside laboratory.

2. The physician group does bill commercial insurance for tests performed but does not mark up the cost of the test; that is, the group bills the exact amount charged by the outside laboratory.

3. The discount arrangement is not, in any way, influenced by the volume of Medicare patient laboratory tests sent to the laboratory facility.

4. The discount arrangement is based upon the volume of laboratory services purchased for HMO patients.

5. An agreement to provide laboratory services to HMO patients at a specified fee or discount that is not based upon volume of Medicare referrals is revenue neutral as far as the Medicare program is concerned. In other words, the fixed discount or specified fee is established completely independently of the volume of Medicare referrals and certainly independently of the Medicare program itself.

Response: We believe that the exception set forth in sections 1877(b)(3) and section 411.355(c) applies in this situation, at least in part. Under those provisions, the prohibition on referrals does not apply to referrals for services furnished by an organization with a contract under section 1876 to an individual enrolled with the organization. (Also see 42 CFR part 417, subpart C.) This exception also applies to referrals for services furnished by organizations with health care prepayment plans that have agreements with us under section 1833(a)(1)(A) to an individual enrolled in the plan (see 42 CFR part 417, subpart D) and by organizations receiving payments on a prepaid basis for their enrollees in accordance with the terms of a demonstration project authorized under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 note). Also, as added by OBRA '93, this exception applies to referrals for services furnished by a qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act) to its enrollees. Thus, the exception no longer requires that all HMO plans contract with Medicare in order to qualify for the exception. The exception in section 1877(b)(3) applies to all services furnished by the organizations listed in that provision, including those services furnished to enrollees by outside physician groups, which have contracted with the organizations. As we noted in earlier responses, we will address the issue of how to treat discounts under section 1877 in the proposed rule covering the designated health services.

b. Forgiveness of Debt; Other Benefits

Comment: One commenter indicated concerns with the inclusion of the term ''forgiveness of debt'' in the definition of remuneration. According to the commenter, there are a number of legitimate reasons why a laboratory might forgive a debt owed by a physician. For example, there might be a dispute over the correctness of a bill or over whether the physician had in fact ordered certain tests. In such instances, a laboratory might decide to write off the debt. In contrast, the laboratory might decide to furnish services to a physician who had previously owed money to the laboratory, which the laboratory had written off. This same commenter recognized that forgiveness of debt in such a situation might be an abuse; that is, the laboratory might simply forgive an obligation owed in order to obtain continued referrals. Thus, the commenter agreed that the forgiveness of debt should be considered remuneration within the meaning of the statute, but added that the definition should distinguish between the atypical situation and routine types of write-offs.

One commenter believed that the inclusion of ''other benefit'' in the definition of remuneration is very broad. The commenter believed the definition could reach a variety of services that are integral to the provision of laboratory services and that enhance the quality of the services furnished. Examples of ''other benefits'' that might be exchanged between a physician and laboratory mentioned by the commenter are test tubes and other laboratory testing supplies, telecommunications equipment such as stand-alone printers, courier services, and educational or consultation services.

Another commenter recommended that the definition of remuneration be amended to exclude from the prohibited category those items or services that are enhancements to the quality of laboratory services and that have no value independent of the laboratory service, such as courier pickup of samples, increased frequency of pick up of samples, and electronic transmission of results.

One commenter recommended that the definition of remuneration be amended to exclude ''discount, forgiveness of debt, or other benefit'' and that we retain the statutory definition.

Response: Section 1877(h)(1) as amended by OBRA '93 specifies that a ''compensation arrangement'' does not include arrangements involving only the following kinds of remuneration:

- The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.
- The provision of items, devices, or supplies that are used solely as follows:

+ To collect, transport, process, or store specimens for the entity providing the item, device, or supply.

+ To order or communicate the results of tests or procedures for the entity.

This provision also excepts payments made by an insurer or self-insured plan to a physician for the physician's claims under certain circumstances.

Thus, we believe that, when a laboratory writes off a debt to essentially correct the records between the parties, the exception described above would apply. However, if a laboratory has a continual pattern of disposing of the debt of its referring physicians in this manner, we might scrutinize the situation under the circumvention scheme provision (section 1877(g)(4).) Negotiations between parties about the correct amount of money owed for services delivered, resulting in a balancing of accounts, would also qualify under this exception, as well as the exchange of certain laboratory supplies, telecommunications equipment, and courier services.

One commenter mentioned that ''other benefits'' exchanged between a physician and a laboratory could be educational or consultation services. Section 1877(e)(3) provides that a physician who has a personal services arrangement (or an immediate family member with a personal services arrangement) with a laboratory entity (for example, to furnish consultations or educational services) may refer patients to that entity if certain conditions are met. Also, section 1877(e)(8)(B) allows a physician to make payments to any entity (including a laboratory) for items and services, other than clinical laboratory services, if the purchase is consistent with fair market value.

Because of these facts, we are retaining the proposed definition of remuneration but are explaining that certain day-to-day business transactions as listed in the statute are not included in this definition.

c. Payments

Comment: One commenter objected to including the term ''payment'' in the definition of remuneration. This commenter pointed out that payments frequently occur between laboratories and physicians and, in many instances, these payments do not create incentives for physicians to order increased laboratory testing. For example, in the commenter's opinion, the following situations do not create incentives for physicians to increase their laboratory referrals.

- The laboratory *pays* a physician who furnishes interpretation or consultation services such as Pap test interpretation, tissue pathology consultations, or EKG holter monitor readings.
- A laboratory *pays* a physician a refund as a result of an overpayment or to settle a disputed claim.
- A laboratory that maintains a self-insured group medical plan for its employees *pays* a physician who furnished services to a laboratory employee.
- A laboratory *pays* a physician to be on call to come to its blood-drawing station in case of an emergency, as required by State law.
- A physician *pays* the laboratory for the provision of a nonlaboratory service that it furnishes or that is furnished by a subsidiary or related corporation, for example, billing, management or consultation services, or the provision of some other medical product or service.

Response: As stated above in response to a similar comment, section 1877(h)(1)(B) provides that, for purposes of determining whether a compensation arrangement exists, the term remuneration includes ''any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.'' One of the definitions found in the American Heritage Dictionary of the English Language for ''remuneration'' is ''payment.'' Therefore, we believe we are correct in concluding that, in general, payments between a laboratory and a physician are a form of remuneration. Arrangements involving remuneration between these parties can, in turn, be characterized as ''compensation arrangements.'' Most, if not all, of the examples provided by the commenter could now fall within specific statutory exceptions. Examples one, three, and four could be excepted under section 1877(e)(3), which excepts certain situations in which an entity pays a physician under a personal service arrangement. The second example could be remuneration that is excepted from the definition of a ''compensation arrangement'' under section 1877(h)(1)(A) and (C), and the fifth example could be excepted under section 1877(e)(8)(B), which excepts payments by a physician to an entity in exchange for items or services other than clinical laboratory services.

We realize that many legitimate transactions occur between laboratories and physicians. We believe that most of these will qualify for the exceptions listed above. But, in the case of continuing arrangements that provide for payment between laboratories and physicians that do not qualify for the exceptions, the prohibition applies.

D. Prohibition on Certain Referrals by Physicians and Limitations on Billing

1. Medicare Only

Comment: One commenter indicated that the final regulation concerning the prohibition should include a statement that a physician's referrals for non-Medicare patients to receive clinical laboratory services, which are not reimbursable under Medicare, are not affected by section 1877 or this rule.

Another commenter requested that the final rule confirm that the statute and the proposed rule do not apply to State Medicaid programs.

Response: In the preamble to the proposed rule (57 FR 8595), we stated that the general prohibition on referrals applies only to referrals for clinical laboratory services that would otherwise be covered by the Medicare program. Therefore, referrals for clinical laboratory services to be furnished to a physician's non-Medicare patients are not affected by section 1877. This concept is reflected in section 411.353(a) of this rule. As a result of section 13624 of OBRA '93, however, section 1877 will have an effect on the Medicaid program beginning with referrals made on or after December 31, 1994. (We plan to address this matter in a separate proposed rule.)

2. Related Parties

Comment: The preamble to the proposed rule (57 FR 8596) states that a financial relationship between a physician and an organization related to an entity that furnishes clinical laboratory services (for example, a parent or subsidiary corporation of the laboratory entity) is to be considered an indirect financial relationship with the entity.

One commenter believed that this concept needs clarification and that it would be helpful to have some ''bright line'' rules for what constitutes a related entity. The commenter asked several sets of questions, which, as we understand them, are as follows:

- Is the related entity concept limited to a parent/subsidiary model or will brother/sister corporations be included?
- Is the relationship between the entities to be defined in terms of a stock ownership requirement and, if so, will a threshold percentage of ownership be required?

In this regard, the commenter suggested that we may want to review the control group concepts set out in sections 414(b) and 414(c) of the Internal Revenue Code of 1986 (IRC) and to consider adopting a similar approach.

Furthermore, the commenter asked questions involving the following situations and suggested that it would be helpful to have specific examples presented in the final rule.

• Twenty-five percent of a clinical laboratory is owned by a professional corporation (P.C.) that, in turn, is owned by five physicians as equal shareholders. The P.C. also employs physicians who are not owners.

—Would a referral to the laboratory by a physician employed by the P.C. be prohibited?

—Would referrals by any of the owners of the P.C. be prohibited?

• Two of the five physician-owners of the P.C. separately own the 25 percent interest in the laboratory rather than the entire P.C.

—Would a referral to the laboratory by a physician employed by the P.C. be prohibited?

—Would a referral by one of the remaining three owners of the P.C. be prohibited?

• A company that is a general partner in a surgery center limited partnership also owns a clinical laboratory. The surgery center has as other limited partners a number of physicians. Can physicians who are limited partners refer patients to the company's laboratory?

Response: First, we want to state that it is not possible to provide specific answers to cover every possible variation of financial relationship. As noted elsewhere in this preamble, we receive a large volume of correspondence. To the extent that there is some uncertainty or confusion concerning a particular provision of the statute or regulation, we are ready to discuss the matter by telephone or in writing. We can, however, only provide our views about general questions; as mentioned previously, we cannot provide formal advisory opinions on specific circumstances.

In regard to the first set of questions, the commenter was concerned about indirect financial relationships with entities. As we explained in an earlier response, we believe that the language of the statute is intended to support indirect, as well as direct, financial relationships, as was specified in proposed section 411.351. In the preamble to the proposed rule, we stated that this would cover financial relationships with an organization related to an entity that furnishes clinical laboratory services. We gave as an example an interest in a parent or subsidiary corporation of the laboratory entity. The commenter's first question was whether the related entity concept was limited to parent/subsidiary situations or whether brother/sister corporations would also be included.

Although the preamble gave the example of a parent or subsidiary relationship between entities, we believe that a physician can have an indirect financial relationship with a laboratory entity under any circumstances in which that physician owns some portion of an entity that has an ownership interest in the laboratory entity. This would be true regardless of whether the entities are related as parent/subsidiary or brother/sister corporations. In other words, these relationships are not the determining factor. For example, a physician's ownership interest might be in a nonlaboratory subsidiary of a parent laboratory corporation. If the physician has an ownership interest in the subsidiary without owning any portion of the parent laboratory, the physician will not be considered to have an ownership interest in the laboratory. The physician would have an ownership interest in the laboratory only if the nonlaboratory subsidiary had an ownership interest (for example, through stock or debt instruments) in the parent laboratory.

We believe the analysis is similar for brother/sister corporations or entities. Subsidiary entities that are related via a common parent may or may not have any ownership interest in each other. If a physician has an ownership interest in a subsidiary that, in turn, has an ownership interest in a brother laboratory, the physician could be regarded as having an indirect ownership interest in the laboratory. However, this would not be the case if the brother/sister corporations have no ownership relationship.

The commenter also asked whether the relationship between entities depends upon stock ownership and, if so, what threshold percentage of ownership is required. The statute in section 1877(a)(2) defines as a financial relationship any ownership interest, regardless of the manner in which the interest is held or the amount of the interest. We believe this rule applies to all ownership interests, whether they are direct or indirect.

Our analysis of corporate relationships would also involve any compensation aspects of the relationships. As we said in the preamble to the proposed rule, any financial relationship between a physician and an organization related through ownership to a laboratory entity could be covered as an indirect financial relationship with the laboratory entity. In addition, even if a physician has an ownership interest in a corporation that has no ownership interest in a laboratory entity, the physician may gain certain financial advantages from the relationship between the nonlaboratory entity and a laboratory that could constitute compensation to the physician from the laboratory. For example, if corporations file as one affiliated company, they may pool their gains and losses for tax purposes. As a result, a physician owner could receive some benefits from the affiliation.

The commenter recommended that we adopt an approach for related entities that is similar to that of the control group concept under the IRC. Generally, under section 414(b) of the IRC, employees of all corporations that are members of a controlled group of corporations (within the meaning of section 1563(a) of the IRC) are treated as employed by a single employer. Under 414(c) of the IRC, all employees of trades or businesses (whether or not incorporated) that are under common control are treated as employed by a single employer. Furthermore, under section 1563(a) of the IRC, a controlled group of corporations generally means the following:

• A parent-subsidiary controlled group is one in which one or more chains of corporations are connected through stock ownership with a common parent corporation.

• A brother-sister controlled group is one in which two or more corporations have five or fewer persons (individuals, estates, or trusts) owning certain levels of stock and controlling certain levels of voting power of all classes of stock entitled to vote.

Since we believe that the statutory language is very broad and encompasses both direct and indirect financial relationships, we cannot accept the commenter's suggestions to use the concept of a control group. Such a concept would narrow the scope of the provisions and would, thus, be inconsistent with the statute.

The commenter raised questions about several specific scenarios. In the first, a P.C. that is owned by five physicians owns 25 percent of a clinical laboratory. The P.C. also employs physicians. Referrals by physician-owners of the P.C. to the laboratory that is owned, in part, by the P.C. would be prohibited, unless an exception applies. Clearly, these five physicians have an ownership interest in the laboratory, even though it is indirectly held through their ownership of the P.C. We also believe that referrals by physician-employees of the P.C. may be prohibited depending upon the following facts. If the P.C. is not a group practice and

employee-physicians are receiving remuneration from the owner physicians for their services as bona fide employees of the P.C., then, under section 1877(e)(2), the remuneration would not constitute a ''compensation arrangement'' if the (e)(2) requirements are met. The remuneration, therefore, would not subject the employee-physicians to the prohibition.

If the P.C. is a group practice, the employee physicians could be considered ''members of the group.'' If so, the referrals of any one member of the group are imputed to the entire group. Because members who are owner physicians in the example may not be able to refer, then neither can the employees, unless an exception applies. If the P.C. is a group practice, the arrangement would need to be evaluated under the in-office ancillary services exception in section 1877(b)(2). That exception does not appear to dictate any particular ownership arrangements between group practice physicians and the laboratory in which the services are furnished. A group practice can take advantage of this exception, and members can refer to each other in the laboratory provided that the group meets the definition of a group practice under section 1877(h)(4). Under the exception in section 1877(b)(2), the services must be furnished by the referring physician or a group member or must be directly supervised by a group practice member. In addition, the services must be billed by the referring physician, the group practice, or an entity wholly owned by the group practice.

In the second scenario involving a P.C., the facts are different. Here two of the five physician-owners of the P.C. have an ownership interest in the laboratory, and this laboratory interest is separate from their ownership of the P.C. Obviously, referrals by those two physicians to the laboratory are prohibited, unless an exception applies. While additional facts surrounding this situation might lead to a different conclusion, it appears that referrals by the remaining three physician-owners of the P.C. and by physician-employees of the P.C. would probably not be prohibited. This is so because, in this case, the P.C. has no ownership interest in the laboratory and the other physicians have no ownership interest. Although the employees are perhaps indirectly compensated by the two owners, their referrals would not be prohibited if their employment arrangement meets the requirements in section 1877(e)(2). If the P.C. is a group practice, however, referrals of any member of a group practice (including owners and employees of the practice) would be precluded, unless an exception applies, such as that in section 1877(b)(2). We stress that this conclusion is based on a minimal amount of information; the conclusion could change if it became apparent that any of the three physician owners or physician employees were receiving any income or compensation, directly or indirectly, from the laboratory. We also stress that sanctions could apply if this turns out to be a circumvention scheme.

Concerning the last question, our analysis of this situation indicates that referrals by limited partner physicians would not be prohibited as long as these physicians do not have a financial relationship with the laboratory or with the company that is a partner in the surgery center. That is, the physicians cannot have an ownership or investment interest in the laboratory itself or the company that owns the laboratory. In addition, there can be no compensation passing between the physicians and the laboratory or between the physicians and the company. When physicians and a company are partners in an enterprise such as a surgery center, their joint ownership does not necessarily mean that there is compensation or payment passing between them; they may simply both be investors. If the arrangement, however, is structured so that there is any compensation passing between the physicians and the company or the physicians and the laboratory, the physician's referrals to the laboratory would be prohibited, provided no exception applies.

Finally, we again remind the commenter that section 1877(g) sets forth sanctions that may be imposed if certain requirements of section 1877 are not met. For example, any physician who enters into an arrangement or scheme that the physician knows or should know has the principle purpose of ensuring referrals by the physician to a particular entity that, if they were made directly, would be in violation of the prohibition, would be subject to the sanctions imposed by section 1877(g).

3. Identical Ownership

Comment: One commenter suggested that group practices may own and operate a laboratory that has been set up as a separate entity. The commenter believed that this arrangement did not appear to be addressed in the proposed regulation. The commenter pointed out that often a group practice will own and operate a clinical laboratory as a separate entity for various financial, liability, and other legal reasons. This commenter believed that there does not appear to be any potential for abuse with these arrangements as long as the separate entity is wholly owned by the group practice or as long as there is identical overlap in ownership. Consequently, the commenter requested that the final rule clarify this point.

Response: As mentioned throughout this preamble, section 1877(a) prohibits a physician who has (or whose immediate family member has) a financial relationship with an entity furnishing clinical laboratory services from referring Medicare patients to that entity unless an exception applies. The statute does not contain a specific exception for wholly-owned entities. The commenter has not provided any evidence to convince us that any entity wholly owned by a group practice is free from program or patient abuse. Thus, we disagree with the conclusion reached by this commenter.

Concerning the commenter's reference to an identical overlap in ownership, we assume the commenter means that the same physicians who own the group practice also own the laboratory. As mentioned above, we do not believe that the Congress intended to except entities that are either wholly-owned or that have an identical overlap in ownership from the referral prohibition. Therefore, unless an exception applies, the physician or group practice owners would be prohibited from referring to a laboratory in which they have an ownership interest.

We believe that in many cases the in-office ancillary services exception in section 1877(b)(2) would apply. For example, physicians in a group practice, as defined in section 1877(h)(4), can refer to a laboratory as long as the laboratory services are furnished personally by the referring physician or by another physician in the same group practice, or under the direct supervision of a physician in the same group practice; in a building that is used by the practice to furnish some or all of the group's laboratory services; and that are billed by the group practice or by an entity that is wholly owned by the group. We believe that this exception applies to any group practice that meets these requirements, regardless of who owns the laboratory, or the manner in which it is owned. Also, services furnished by a rural laboratory would be exempted, regardless of the circumstances of ownership.

4. Technical Change

Comment: One commenter recommended that the phrase ''under that referral'' at the end of proposed § 411.353(b) be changed to ''under that

referral that is prohibited by paragraph (a).''

Response: We do not agree that this change is necessary, since ''that referral'' refers back to the earlier part of the sentence, which says ''that is prohibited by paragraph (a) * * *.''

5. Refunds

Comment: One commenter indicated that it is not unreasonable for an ''entity that collects payment'' to be required to make refunds in accordance with these regulations. The commenter believed, however, that the regulations provide no ability for the ''entity that collects payment'' to obtain the information needed to determine whether it is required to make a refund. The commenter suggested that the regulations either explicitly provide the means for the entity that collects payment to obtain the requisite referral information from the physician ordering the service or hold it harmless for refunds it does not make because it does not have the needed information.

Response: We do not agree with this comment. A laboratory is responsible for knowing with whom it has a financial relationship. Under section 1877(f) and our rule at § 411.361, laboratory entities are required, as specified by us, to provide us with information concerning their financial relationships, including ownership and compensation arrangements and including the names and unique identification numbers of all physicians with financial relationships or whose immediate relatives have financial relationships. Additionally, under the CLIA rules at § 493.634, laboratories are required to provide and update ownership information.

E. General Exceptions to Referral Prohibitions Related to Ownership and Compensation

1. Physicians' Services

We proposed that the prohibition on referrals does not apply to physicians' services that are furnished personally by (or under the direct personal supervision of) another physician in the same group practice as the referring physician.

Comment: One commenter indicated that the proposed rule states that exempt physicians' services would have to be performed in the group practice's office. The commenter questioned whether the exception should be so limited. The commenter believed that if physicians' services, as that term is defined in the proposed rule, are performed in another entity furnishing clinical laboratory services for a group practice, the exception should apply as long as the physician performing the physicians' services and the referring physician are members of the same group practice. In other words, in the commenter's opinion, the physicians' services exception should apply regardless of whether the clinical laboratory is a group practice laboratory or a laboratory owned by another entity with which the group practice has a financial arrangement.

Response: We agree, in part, with this commenter. This exception applies to a limited number of services, that is, clinical laboratory services that are treated as physicians' services for Medicare purposes in the context of a group practice. We believe that the services can be performed anywhere and under any circumstances as long as they qualify as ''physicians' services'' and are personally performed or personally supervised by another group practice member and do not otherwise result in a prohibited referral. Thus, physicians' services furnished by group practice physicians do not need to be furnished in group practice offices, provided they meet the other requirements in the statute.

2. In-Office Ancillary Services

Based on the provisions of OBRA '89, we explained in the proposed rule that the prohibition on referrals would not apply to in-office ancillary services if the following conditions are met:

- The services are furnished personally by one of the following:
  + The referring physician.
  + A physician who is a member of the same group practice as the referring physician.
  + Nonphysician employees of the referring physician or group practice who are personally supervised by the referring physician or by another physician in the group practice.
- The services are furnished in one of the following locations:
  + In a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of clinical laboratory services.
  + In the case of a referring physician who is a member of a group practice, in another building that is used by the group practice for centrally furnishing the group's clinical laboratory services.
- The services are billed by one of the following:
  + The physician performing or supervising the services.
  + The group practice of which the referring physician is a member.
  + An entity that is wholly owned by the physician or the physician's group practice.

(As discussed later in this preamble, OBRA '93 made significant changes to the in-office ancillary services exception (section 1877(b)(2).)

a. Referrals From Physicians Who Do Not Have a Financial Relationship With the Physician or Group Practice

Comment: One commenter suggested that a significant loophole is created in the proposal by exempting from the referral prohibition certain services provided by the referring physician, under his or her direction, or under the direction of others in the same group practice. The commenter suggested that, under this proposal, a group practice could establish a laboratory in its own office and accept referrals from outside physicians not associated with the group practice. The commenter believed that the acceptance of such referrals from physicians outside the group should result in that laboratory being considered an independent clinical laboratory owned by the physicians in the group. Therefore, the commenter believed that, under the terms of section 1877, the laboratory should no longer be permitted to accept referrals from the outside.

Some other commenters believed that the exemption for in-office ancillary services was adopted with the understanding that clinical laboratory services would be limited to the physicians' or group practices' own patients. According to these commenters, the regulations implementing the legislation should reflect this intent and specifically require that the exception apply only to physician office laboratories that do not accept referrals from physicians outside of the practice.

Another commenter believed that exempted group practice laboratories should meet the following two conditions:

First, the group practice laboratory should be fully financially integrated with the group practice, such that all group members and only group members share in laboratory expenses and income, and those expenses and income are distributed among group members in precisely the same manner and proportion as professional fees and expenses.

Second, the group practice laboratory should not be allowed to accept referrals of any tests from nongroup members.

This commenter believed that these restrictions would guarantee that the laboratory is in fact an extension of the group practice and not a distinct

business operating under the protection of the group practice.

On the other hand, another commenter recommended that we definitively state in the final rule that furnishing laboratory services on referral from outside sources will not disqualify a group practice laboratory from the in-office ancillary services exception if the laboratory meets all of the performance standards set forth in the definition of ''group practice'' in the statute and the proposed rule.

Response: There are two distinct issues that need to be addressed in responding to these comments. The in-office ancillary services exception in section 1877(b)(2) provides that the prohibition on referrals will not apply to those services that are furnished personally by the referring physician, a physician in the same group practice as the referring physician, or by individuals who are (as amended by OBRA '93 and effective on January 1, 1992) directly supervised by the physician or another physician in the same group practice. This exception further contains location and billing criteria. It is our belief that this exception was provided for those clinical laboratory services that are performed as an adjunct to the patient care services of the attending physician. As such, the solo physician, the group practice, or an entity that is wholly owned by the physician or group practice must bill for the services.

On the other hand, the general prohibition on referrals applies only to referrals for clinical laboratory services made by a physician to an entity with which he or she or an immediate family member has a financial relationship. Section 1877 does not prohibit either a solo practitioner's laboratory or group practice laboratory from accepting referrals from outside physicians who do not have a financial relationship with the laboratory. When the solo practitioner or group practice, however, accepts referrals from sources outside of its office practice, the office laboratory is also acting as an independent laboratory because these services are not performed as an adjunct to the patient care services of the attending physician. As a result, the laboratory must have a billing number from the Medicare carrier and directly bill for the services that are performed on referral.

A physician or group practice cannot bill for the laboratory services furnished to the patients of another physician as if they were the physician's or group's own patients, under the physician's or group's provider number.

To summarize, we do not find anything in section 1877 that would prohibit a physician or group practice office laboratory from accepting referrals from physicians who do not have a financial relationship with the laboratory, physician, or group. However, if such referrals are accepted, they cannot be billed by the physician or group practice. Rather, billing must be done under a billing number that is assigned by the Medicare carrier to the laboratory itself.

We would also like to point out that, if a member of the group is either performing or supervising the laboratory services, the quantity of outside tests could affect the group's ability to qualify as a ''group practice'' under the definition in section 1877(h)(4). Under (h)(4)(A)(ii), substantially all of the services of physician members (who now include any physicians during the time they work for the group) must be provided through the group and be billed in the name of the group (beginning January 1, 1995, these services must be billed under a billing number assigned to the group). If group practice members spend too much time supervising laboratory tests that are billed under the laboratory's separate number, the group practice could fail to meet the ''substantially all'' test.

b. Independent Group Practice Laboratories

Comment: One commenter indicated that, while the point was not addressed in the proposed rule, we issued guidance to the carriers to deal with situations in which a group practice laboratory is also certified as an independent laboratory. The commenter wrote that we stated that the services must be billed differently depending on whether the test was referred for a patient of the group, or the test was referred from outside the group. The commenter suggested that it would be simpler for the groups and the government to have all services (physician, laboratory, and otherwise) billed to Medicare under one group billing number, regardless of the origin of the patient.

Response: We do not agree with this commenter. It has been an established Medicare policy that a laboratory a physician or group practice maintains solely for performing diagnostic tests for its own patients is not considered an ''independent'' laboratory. This means that the solo practicing physician or group practice can bill for in-office laboratory testing using the physician's or group practice's own billing number. Conversely, a physician providing clinical laboratory services to patients of other physicians is considered not to be furnishing ''in-office ancillary'' services and is, therefore, doing business as an independent laboratory. Since this policy has been in effect for over a decade, we believe that physicians or group practices that have been accepting referrals from outside physicians have already established that the laboratory is a separate entity for those tests and they are familiar with the billing rules.

Furthermore, as previously explained, section 1833(h)(5)(A) indicates that payment may be made only to the person or entity that performed or supervised the performance of the tests. There are several exceptions to this rule, including one in which, if a physician performed or supervised the performance of the test, payment may be made to another physician with whom he or she shares a practice. This would apply, for example, if the two members are members of a group practice. Taking these factors into consideration, we affirm that physicians and group practices can bill, under their provider number, for clinical laboratory services performed only for their own patients. If the physicians' or group practices' in-office laboratory also provides reference work for patients of other physicians, that laboratory entity must bill for the services directly under its own number.

c. Furnishing of Tests

Comment: One commenter indicated that the final regulations should provide further guidance regarding the scope of the term ''furnished.'' For instance, the commenter understood that we take the position that consulting services designed to assist a physician in interpreting test results are not considered a part of the furnishing of the clinical laboratory test; rather, these services are considered to be physicians' services. The commenter further understood that we take this position even though interpretation services are included in the Medicare payment for the laboratory service and Medicare makes no other payment for the physician's interpretation services.

Response: At § 411.353(a) in the proposed rule, we defined clinical laboratory services for purposes of section 1877 as those services described in the CLIA regulations at § 439.2. Thus, a service would be covered under section 1877 as a ''clinical laboratory service'' only if the service is considered a clinical laboratory service under CLIA.

Some services may be billed as, for example, physician's services but they would still be subject to CLIA (and, as a result, to section 1877) if they fall within the scope of services described in § 493.2. This is so regardless of how they are billed. Under § 493.2, a laboratory means a facility for ''the

biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings.'' In short, the services covered under CLIA and section 1877 are those conducted by these facilities and involving the examination of materials derived from the human body.

The commenter has asked specifically about consulting services designed to assist a physician in interpreting test results. We believe that CLIA covers the actual examination of materials, their analysis, and any interpretation and reporting of the results which are performed by a facility that qualifies as a laboratory, as defined in § 493.2. If a laboratory interprets certain test results or hires a consultant who takes the responsibility to interpret them in lieu of laboratory personnel, we believe the interpretation would qualify as a clinical laboratory service. (If a consultant only offers input or information which the laboratory will use in making its own interpretation, the input would not qualify as a clinical laboratory service.)

However, if a laboratory sends test results to an independent physician, any interpretation performed by the physician would not be performed by the laboratory facility. As a result, the services would not constitute part of the clinical laboratory test. If a physician hires a consultant to help interpret the results, the same rule would apply: the consultant's services would not constitute clinical laboratory services if the consultant is performing outside the auspices of a laboratory facility. The services would not be subject to CLIA or section 1877.

If, on the other hand, a physician or group practice hires a consultant to perform, analyze or interpret test results that are performed in the physician's or group's own laboratory, the interpretation would qualify as part of the services performed by a laboratory. These interpretive services would be subject to CLIA and, as a result, to section 1877. If the physician or group practice wishes to qualify under the in-office ancillary services exception, the physician or member of the group practice must supervise any non-physician consultant when he or she performs clinical laboratory services. In addition, the tests must meet the section 1877(b)(2) location and billing requirements.

d. Services an Outside Laboratory May Provide to a Physician's Office Laboratory

Comment: One commenter had concerns about services a laboratory outside the physician's office may provide a physician's office laboratory. The commenter wrote that the final CLIA regulations contain personnel standards that require laboratories performing moderately complex testing to have a laboratory director, a technical consultant, a clinical consultant, and testing personnel who meet certain standards. (See 42 CFR part 493.) In physician office laboratories, for the most part, one of the practice's physicians will function as the laboratory director and also may function in one or more other roles. In some circumstances, however, physicians have asked an independent laboratory entity to serve in, or assist the physician in carrying out the duties of, one of the required positions to the extent permitted under CLIA. For example, an independent entity might serve as the clinical consultant for a number of its physician customers as well as assist a physician in carrying out the duties of the technical consultant. The commenter requested a clarification in the final regulations that such services would not defeat a physician office laboratory's qualification for the in-office ancillary services exception, since the independent contractors will not be employees of the physician.

The commenter believed that, since all laboratories, including physicians' office laboratories, must meet the CLIA standards, the laboratory testing performed in these laboratories is covered under the provisions found in section 1861(s)(3). Since section 1861(s)(3) does not have an employment requirement, the commenter concluded that the physician does not have to employ the personnel as he or she would if the laboratory services were billed and covered as services performed incident to the professional services of the physician under section 1861(s)(2)(A).

Response: Regardless of the setting in which it is performed, if a service involves laboratory tests on human specimens by a laboratory as defined in § 493.2, the CLIA provisions apply. So we agree that the CLIA requirements apply to in-office laboratories of solo-practicing physicians and of group practices. It appears that the commenter is concerned about the requirement in the predecessor provision at section 1877(b)(2) that, in order for the in-office ancillary services exception to apply, services, when not furnished by a member physician, must be performed by individuals who are *employed* by the physician or the group practice. The employment requirement was eliminated by OBRA '93 retroactively to January 1, 1992. Therefore, under amended section 1877(b)(2), referrals for services to be furnished by any individuals who are directly supervised by the referring physician or, in the case of group practices, by another physician in the same group practice, are excepted. In other words, the in-office ancillary services exception applies to a physician or group practice that has outside contractors furnishing laboratory services, as long as the physician or group practice physicians directly supervise these individuals. In addition, as mentioned previously, a contracting physician may be considered a ''member'' of a group practice. As a member, the contractor could perform the services without supervision or directly supervise other individuals who perform clinical laboratory services.

Also, in this regard, we have taken the position in the past that clinical laboratory testing performed in physicians' offices is covered only if furnished by the physicians or if the requirements are met for coverage of services incident to the professional services of the physicians under section 1861(s)(2)(A) (see section 2070 of the Medicare Carriers Manual (MCM)). One of the requirements has been that persons performing services incident to the services of a physician must be employed by the physician. However, section 1861(s)(3) states, in pertinent part, that ''medical and other health services'' covered by Medicare include ''diagnostic laboratory test[s].'' Section 1861(s)(3) does not exclude diagnostic tests performed in physicians' offices or clinics. The only restriction on coverage under section 1861(s)(3) is set forth in the language following section 1861(s)(14), which states that ''[n]o diagnostic tests performed in any laboratory * * * shall be included within paragraph (3) unless such laboratory'' meets the CLIA certification requirements or has a certificate of waiver. Because section 1861(s)(3) relates more specifically to laboratory testing than section 1861(s)(2)(A), and because most laboratory testing performed in a physician's office is subject to CLIA, we now take the position that it would be appropriate to provide coverage of these services under section 1861(s)(3). (We are in the process of changing the MCM to reflect this position.) This means that the employment requirement does not have

to be met for purposes of coverage or for purposes of application of the in-office ancillary services exception.

Furthermore, we note that section 1877(e)(8)(B) provides an exception for physicians who contract with an entity outside of their office for items or services, providing the items or services are furnished at a price that is consistent with fair market value. Fair market value is defined in section 1877(h)(3) as meaning the value in arm's-length transactions, consistent with the general market value.

We believe this exception permits a physician to contract with a laboratory outside of his or her office for certain services and to continue to refer testing to that laboratory, providing the services meet the requirements for fair market value. Therefore, an independent laboratory entity will be able to provide personnel to assist a physician in carrying out the CLIA requirements.

Accordingly, from the circumstances described by the commenter, the following conclusions emerge:

- In order to comply with the CLIA requirements, a physician or group practice may contract with a laboratory for the services of various physicians or other personnel. In these cases, as long as the direct supervision requirement is met, application of the in-office ancillary services exception is not jeopardized by the fact that the personnel performing the CLIA-related activities are not employed by the physician or group practice.
- Physicians' referrals to the laboratory with which they contract for the performance of CLIA-related activities will not be prohibited if the contract meets the ''fair market value'' requirement of the exception found in section 1877(e)(8)(B).

e. Location

Comment: One commenter believed the location requirements of the in-office ancillary services exception arbitrarily distinguish between group practices and solo practitioners. The commenter stated that a referring solo physician, as well as a group practice, should be able to qualify under this exception if the laboratory is located in a building used for centrally furnishing clinical laboratory services. The commenter believed there is no remedial purpose served by requiring that a laboratory with which a solo practitioner has a financial relationship be in the same building as his practice, while permitting a laboratory with which a group practice has a financial relationship to situate the laboratory in a separate building.

Response: We believe that, in creating the exception in section 1877(b)(2) and entitling it ''in-office ancillary services,'' the Congress meant to except situations in which a physician refers patients to the practice's own laboratory located in the physician's practice office, or nearby. As a result, the statute requires that the services be furnished in a building in which the referring physician furnishes physician's services unrelated to clinical laboratory services.

Congress, however, has apparently always regarded the same building requirement as too restrictive for a group practice. Before the enactment of OBRA '93, section 1877(b)(2)(A)(ii)(II) allowed a group practice to refer to a laboratory in another building that was used by the group practice for the centralized provision of the group's clinical laboratory services. OBRA '93 liberalized this provision even more, amending it to allow a group practice to refer to another building that is used for some or all of the group's clinical laboratory services, no longer requiring that the services be performed in a ''centralized'' laboratory. This provision is effective retroactively to January 1, 1992.

Because group practices can have practice offices in many locations, the Congress appears to believe that it could be difficult to locate the group's laboratory close to all of them. The legislative history for the OBRA '93 amendment points out that a number of group practices own and operate satellite facilities in communities other than the community in which the main clinic facility is located. (H.R. Rep. No. 111, 103d Cong., 1st Sess. 545 (1993))

We have not created an exception under section 1877(b)(4) for solo practitioners who refer to laboratories that are located in buildings other than the ones in which they practice. That is so because we believe the services would cease to be in-office ancillary services if they are referred to an outside location and the solo practitioner might be less likely to directly supervise the services. Also, we have seen no evidence that such an exception would be free from any risk of patient or program abuse.

3. Prepaid Health Plan Enrollees

Under § 411.355(c) of the proposed rule, the prohibition on referrals does not apply to services furnished by one of the following organizations to its enrollees:

- An HMO or a CMP that has a contract with us under section 1876 and 42 CFR part 417, subpart C.
- A health care prepayment plan that has an agreement with us under section 1833(a)(1)(A) and 42 CFR part 417, subpart D.
- An organization that is receiving payments on a prepaid basis for enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 note).

OBRA '93 amended section 1877(b)(3) to also include services furnished by a qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act) to an individual enrolled with the organization.

Comment: One commenter indicated that the HMO exemption appears to be available only for a narrowly defined group of HMOs. The commenter recommended broadening this exemption because HMOs employ utilization review criteria and these criteria serve as a disincentive to overutilize services.

Response: As mentioned above, OBRA '93 provided an exception for referrals to qualified HMOs for the provision of services to enrollees of the HMO. This exception would apply to referrals for Medicare beneficiaries to Federally-qualified health maintenance organizations (FQHMOs) without requiring the FQHMO to enter into a contract under section 1833 or 1876.

Comment: One commenter indicated that the final regulation should permit staff physicians of a Medicare-contracting HMO or competitive medical plan (CMP), or a health care prepayment plan (HCPP) operated under an agreement with HCFA, to refer Medicare beneficiaries to their affiliated clinical laboratories, regardless of whether the beneficiary is enrolled as a member of the HMO/CMP/HCPP.

This commenter presents the case of an entity that contracts with us to furnish covered services to Medicare beneficiaries as an HCPP under section 1833(a)(1)(A). Medical services furnished by the HCPP are predominantly provided at clinic locations by employee and independent contractor physicians. The commenter believed that the proposed regulation would require the clinics to establish two different protocols for their laboratory services: one for their HCPP enrollees and one for Medicare eligible patients who are not enrolled as members of the HCPP, and on whose behalf Medicare pays on a fee-for-service basis (''fee-for-service patients''). The commenter believed this distinction is artificial and could result in different levels of care for certain classes of Medicare beneficiaries. The distinction

should, in the commenter's opinion, be eliminated.

Additionally, the commenter believed that providing a broader exception for referrals by HMO, CMP, or HCPP staff physicians is consistent with the statutory exemptions for services furnished by these organizations. The HMO, CMP, or HCPP exception recognizes that managed care plans may properly organize and operate their own clinical laboratories in the interest of serving their patients efficiently and economically. Those organizations may require their physicians to refer certain clinical laboratory services for both enrolled members and fee-for-service patients to their affiliated laboratories.

Even HMOs, CMPs, and HCPPs that engage physicians to practice in facilities owned and operated by the HMO, CMP, or HCPP may furnish services to Medicare beneficiaries who are not enrolled as members. Often this occurs when a patient ''walks in'' to the HMO, CMP, or HCPP clinic or when a relative accompanies a person who is enrolled in the plan.

The commenter believed that no purpose would be served by requiring physicians in HMOs, CMPs, or HCPPs that operate clinical laboratories to refer services for Medicare beneficiaries who are not enrollees to another laboratory. The commenter stated that these nonenrollee patients should be entitled to expect the same level of care as enrollees.

Response: As we have noted earlier, OBRA '93 added to the list of prepaid plans in the section 1877(b)(3) exception an organization that is a qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act). The statute specifically excepts from the physician referral prohibition only services furnished by the listed organizations *to their enrollees.* Our proposed and final regulation reflect this statutory limitation. We decline to add services furnished to non-enrollees as an additional exception under section 1877(b)(4). When HMOs, CMPs, and HCPPs are reimbursed by Medicare on a fee-for-service basis, we believe that there still exists an incentive for these organizations to overutilize services. The Secretary cannot create an additional exception unless she determines that there is *no* risk of patient or program abuse.

However, physicians who are employed by HMOs, CMPs, and HCPPs may still be able to refer non-enrolled patients to the laboratories that are affiliated with these organizations under other exceptions in the statute. For example, if the physicians only receive compensation from these organizations under an employment agreement or personal services contract, they can refer to the organizations' laboratory if they meet the requirements in section 1877(e)(2) or (e)(3).

F. Exceptions to Referral Prohibitions Related to Ownership or Investment Interest

1. Publicly-Traded Securities

In proposed § 411.357(a), we provided that physicians who hold an ownership or investment interest in certain entities may make referrals to those entities if the following requirements are met:

- The physician purchased ownership of the entity in the form of investment securities (including shares or bonds, debentures, notes or other debt instruments) on terms generally available to the public.
- The ownership or investment interest is in a corporation that meets the following conditions:

+ It is either listed for trading on the New York Stock Exchange or the American Stock Exchange or is a national market system security traded under an automated interdealer quotation system operated by the National Association of Securities Dealers.

+ It had, at the end of its most recent fiscal year, total assets exceeding $100 million. These assets must have been obtained in the normal course of business and not for the primary purpose of qualifying for this exception.

As we have discussed elsewhere, OBRA '93 modified section 1877(c) in several ways. First, investment securities no longer have to be those purchased on terms generally available to the public; they must only be those which ''may be purchased'' on terms generally available to the public. Second, the securities can be those listed on additional exchanges. Third, the investment securities no longer have to be in a corporation with $100 million in total assets at the end of a fiscal year; now the holdings of the corporation must be measured in terms of ''stockholder equity,'' and the amount has been modified from $100 million to $75 million. This amount can now either be measured at the end of the most recent fiscal year or be based on the corporation's average during the previous 3 fiscal years. Finally, OBRA '93 extends the exception to apply to certain mutual funds.

Under the effective date provisions of OBRA '93, the amended version of section 1877(c) was not effective until January 1, 1995. SSA '94 revised this effective date provision to make the amended version of section 1877(c) effective retroactively to January 1, 1992; however, the revised effective date provision states that, prior to January 1, 1995, the amended § 1877(c) does not apply to any securities of a corporation that meets the requirements of § 1877(c)(2) as they appeared prior to OBRA '93. Section 1877(c)(2), prior to OBRA '93, contained the requirement that a corporation have $100 million in total assets.

Comment: One commenter supported our proposed requirements. The commenter believed that the additional requirement concerning the purpose in obtaining assets will help eliminate certain obvious sham transactions that followed the passage of section 1877. The commenter suggested the inclusion of additional language requiring that these entities have $50 million in shareholder equity. Such a threshold, according to the commenter, could help to ensure that the company has actual, hard assets, rather than simply ''phantom'' assets that are offset by significant liabilities.

Response: After consideration of the comments we received on this issue (see below), we have decided that it would be extremely difficult to prove exactly what a corporation intended when it decided to acquire assets; that is, to sort through a corporation's financial records to try to separate business purposes from nonbusiness purposes. We further believe that it would be difficult to define what is meant by ''acquiring assets during the normal course of business.'' Therefore this final rule does not specify that the assets must have been obtained in the normal course of business and not for the primary purpose of qualifying for the exception.

We agree that the commenter's suggestion for ''shareholder equity'' is a good one, but we do not believe that the Congress meant to refer to this concept when it included the term ''total assets'' in the statute. That is so because the OBRA '93 amendments specifically replaced the concept of ''total assets'' with ''stockholder equity,'' a change the legislative history describes as a modification of the law and not a clarification or explicit expression of what was already implicitly present in the law. Also, the fact that SSA '94 appears to make the $100 million-total-asset-standard and the $75 million-stockholder-equity- standard apply simultaneously until January 1, 1995 suggests that they are two different concepts. Beginning on January 1, 1995, the ''stockholder equity'' standard will prevail.

Comment: Another commenter wished to emphasize the requirement that, in order to qualify for the exception, the general public must have the same opportunity to buy and sell the entity's stock as physician-investors. As noted in the proposed rule, physician-partners in a laboratory should not be permitted to exchange their partnership shares for stock in a new corporation, which is then publicly traded at some later date. The commenter was aware of one entity that has purchased physician-owned laboratories in just this manner. Therefore, the commenter believed that we should emphasize that such conduct is a clear violation of the regulation.

Response: The requirement at issue in the regulation was derived from section 1877(c), as it appeared prior to OBRA '93. Section 1877(c) used to require that investment securities be those *which were purchased* on terms generally available to the public. OBRA '93 amended this provision (the amendment is now retroactively effective as a result of SSA '94) to say that the investment securities are those which *may be purchased* on terms generally available to the public. We will interpret the amended provision and other provisions in OBRA '93 in a proposed rule covering all of the designated health services.

Comment: A few commenters indicated that they disagree with the proposed requirement that the $100 million in assets must have been obtained in the normal course of business and not for the primary purpose of qualifying for this exception. The commenters believed there is no evidence that the Congress intended to deny protection to entities that meet the $100 million asset test in part or in whole by acquiring assets for the purpose of qualifying for the exception spelled out explicitly in section 1877(c). The commenters suggested that the purchase of an independent clinical laboratory by a corporation intending to include the purchase in the total assets needed to qualify for this exception is not clearly an example of a corporation trying to circumvent the law through a sham transaction. One commenter went on to state that any corporation and physician involved in a good faith purchase and sale of a clinical laboratory in order to comply with the law would be unfairly penalized by the proposed language.

A few commenters urged that we eliminate the statement in the preamble advising the OIG to treat as a circumvention scheme any effort by an entity to obtain $100 million principally for the purpose of meeting the ''$100 million in total assets'' test.

Response: As mentioned in a previous response, we are withdrawing this interpretation and requiring that the corporation meet one of the following criteria: (1) it has, at the end of its most recent fiscal year or, on average during the previous 3 fiscal years, stockholder equity exceeding $75 million or (2) until January 1, 1995, it had, at the end of its most recent fiscal year, total assets exceeding $100 million, irrespective of how those assets were obtained.

The statement that the commenters have asked us to eliminate appears in the preamble to the proposed rule at 57 FR 8600 in the discussion on OIG regulations. Since we are not including a requirement about how the assets are obtained, we are not including language related to this issue in the final rule.

Comment: One commenter indicated that a major ambiguity appears in this exception when one considers how to treat physician investors who have acquired shares prior to the time the laboratory was publicly traded. As written, the statutory exemption might be interpreted not to protect such previously acquired shares since, by definition, they were not acquired in a transaction involving the general public.

The commenter requested that the final regulations specify that, once the laboratory meets both of the exemption's tests (that is, the stock exchange listing and the level of assets criteria), physicians who acquired their shares before this time be permitted to refer patients under certain conditions. That is, physicians can refer provided they own only shares with rights identical to those generally available to the public through trading on one of the specified exchanges.

Response: As we have pointed out in earlier responses, the requirement in the proposed regulation has been modified to reflect the statute, as amended by OBRA '93. OBRA '93 amended this provision (the amendment is now retroactively effective as the result of SSA '94) to say that the investment securities are those which *may be* purchased on terms generally available to the public.

Comment: One commenter requested that we use the same definition of public company that it believes is used by the Securities and Exchange Commission (SEC); that is, the definition used under General Accepted Accounting Principles. The commenter believed that use of this commonly accepted definition is in accord with the ''public company'' intent of the legislation and will maintain the ''bright line'' between referrals that can and cannot be influenced by ownership position.

Response: The American Institute of Certified Public Accountants, Inc., defines a public enterprise as a business enterprise—

- Whose debt or equity securities are traded in a public market on a domestic stock exchange or in the domestic over-the-counter market (including securities quoted only locally or regionally); or
- That is required to file financial statements with the SEC.

An enterprise is considered to be a public enterprise as soon as its financial statements are issued in preparation for the sale of any class of securities in a domestic market. (Commerce Clearing House, Professional Standards, AC Section 1072, 024(h).)

We do not believe that this definition adds any clarity to the very specific requirements found in the law; that is, for purposes of section 1877(c), a corporation is an entity that is listed for trading on the New York Stock Exchange or on the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis, or is a national market system security traded under an automated interdealer quotation system operated by the National Association of Securities Dealers.

Comment: One commenter suggested we allow the use of a consolidated balance sheet to show that the $100 million asset test is met.

Response: A consolidated balance sheet is used for financial reports for a group of affiliated corporations, eliminating intercorporation debts and profits and showing minority stockholders interest. It also is used when, under certain circumstances, multiple related entities must report balances in a combined fashion instead of separately.

Since the statute excepts investment interests in a corporation with a minimum amount of assets (or, under OBRA '93, stockholder equity), we do not believe it is appropriate to aggregate the assets of multiple corporations on a consolidated balance sheet.

In the preamble to the proposed rule (57 FR 8597), we stated that the $100 million in assets requirement applies only to the corporate entity that furnished the clinical laboratory services, and it does not include assets of any related corporations. This statement is misleading in that it applies only when the stock ownership giving rise to the financial relationship is held in the corporate entity that furnishes clinical laboratory services; it is

incorrect when applied to stock ownership in a corporation that does not itself furnish clinical laboratory services. In the latter case, the assets requirement would apply to the parent corporation (the corporate entity in which the stock is held), not to the subsidiary laboratory corporation.

Therefore, we are clarifying that only the assets of the corporation in which the physician or immediate family member's stock is held may be counted to determine whether the $100 million asset requirement (or $75 million in stockholder equity requirement) is met under section 1877(c)(1).

Comment: One commenter indicated that we should permit the grandfathering of financial transactions that were entered into to meet the intent of the legislation with regard to the $100 million asset test if they were entered into before the effective date of the regulations. The commenter believed that such grandfathering would ease accounting and reporting requirements. Further, the commenter suggested that the final regulations should apply to an organization's fiscal year beginning after the effective date of the rule.

Response: As discussed earlier in this preamble, we are withdrawing our interpretation concerning how a corporation had to have obtained its assets.

In regard to the commenter's suggestion that the final regulations should apply to an organization's fiscal year beginning after the effective date of the rule, we disagree. Section 1877(c)(2), prior to its amendment by OBRA '93, required that a corporation have, at *the end of the corporation's most recent fiscal year,* total assets exceeding $100 million. The amended version of this provision requires that a corporation have, *at the end of the corporations' most recent fiscal year, or on average during the previous 3 fiscal years,* stockholder equity exceeding $75 million. These statutory provisions require an assessment of a corporation's assets or equity based upon a past year or years. These provisions were effective retroactively to January 1, 1992. We do not believe they can be interpreted to require compliance in the fiscal year occurring subsequent to the publication of this final regulation.

2. Rural Laboratories

In proposed section 411.357(b), we stated that an ownership or investment interest in a laboratory that is located in a rural area will not prohibit the physician owners from making referrals if the following criteria are met:

- The laboratory testing that is referred by a physician who has an ownership or investment interest in the rural laboratory must either—
  + Be performed on the premises of the rural laboratory; or
  + If not performed on the premises, the laboratory performing the testing must bill the Medicare program directly for the testing.
- The majority of tests referred to the rural laboratory must be referred by physicians who have office practices located in a rural area.

As mentioned in response to a previous comment, we have amended the standards for this exception by eliminating the requirement that a majority of tests referred to the rural laboratory must be referred by physicians who have office practices located in a rural area. Instead, we are adopting the standard required by OBRA '93 that substantially all of the clinical laboratory services furnished by the entity are furnished to individuals residing in such a rural area.

a. General

Comment: One commenter indicated support for our formulation of the exception applicable to laboratories located in a rural area. The commenter was aware of a number of laboratories that were established in rural areas but that serve physician-owners and patients located in large metropolitan areas.

Another commenter stated that this exception protects against abuses by laboratories in rural areas, such as the setting up of a ''shell'' laboratory with a rural address. This commenter also supported the proposed rule's mandate that at least 51 percent of the tests referred to a rural laboratory be referred by rural doctors. The commenter believed this requirement should help to ensure that the laboratory is in fact serving rural beneficiaries.

On the other hand, a third commenter proposed that the final rule adopt an expanded definition of rural area that would include towns or similar State governmental subdivisions if the population is below 10,000 people and a laboratory located in the area meets the 2 additional requirements set out in the proposed rule. As an additional criterion, the commenter suggested that governmental subdivisions meeting this population standard could be defined as ''rural'' only if the number of outpatient laboratories in the area was no more than two. The commenter believed that this additional criterion would identify those laboratories that are clearly essential to serving the patient needs of the community.

Response: We agree with the first two commenters and believe that the OBRA '93 amendment imposing the requirement that ''substantially all'' of a rural laboratory's services be performed for residents of the rural community indicates that the Congress is aware of and is concerned about the potential for abuse in this area.

What the third commenter urges is recognition of a laboratory entity as a rural provider, despite the fact that the entity is located within a metropolitan statistical area (MSA), if the suggested conditions are met. While we recognize that there may be some laboratory entities located in MSAs that, by virtue of being located in small towns within an MSA, have experiences similar to laboratories located in rural areas, we believe that it would be difficult in any given case to prove that the laboratory's situation actually parallels the situation in a rural area. In addition, it would be difficult and burdensome to make these determinations on a case-by-case basis. Further, at this time, we have no evidence that opening this exception to ''nonrural'' laboratories would be free of any risk of program or patient abuse, the standard that must be met under section 1877(b)(4).

b. Percentage of Tests and Direct Billing

Comment: One commenter argued that the exception for clinical laboratories in rural areas is too stringent. The commenter was concerned that the proposed requirement that more than 50 percent of the tests performed be referred by physicians whose practices are located in rural areas may present an undue burden on already existing rural laboratories. Those rural laboratories may be forced to close because their viability comes from nonrural business. Thus, the commenter recommended grandfathering existing rural laboratory practices.

Response: Although we have changed the proposed rule, the rule still requires that ''substantially all'' of a laboratory's services be furnished as rural business. As we explained previously, we believe to meet this standard that at least 75 percent of the clinical laboratory services must be furnished to individuals who reside in a rural area. Section 1877 does not contain an overall ''grandfather'' clause which would allow laboratory facilities that existed prior to its effective date to continue to accept prohibited referrals just because the laboratories predate the statutory provision. In addition, the statute does not routinely excuse certain referrals because it would be a burden for a facility to alter its business practices in order to fit within an exception. We believe that, instead, the specific

purpose of the statute is to require laboratory facilities to alter their practices in order to avoid abusive or potentially abusive financial relationships. Our approach in the proposed and final regulation for this provision reflects that purpose.

Furthermore, we do not believe that we can specifically except from the prohibition rural laboratories whose viability depends on non-rural business. We do not know at this time how many rural laboratories would have extreme difficulty meeting the requirements in the proposed regulation. Also, as described in previous comments, the situation described by the commenter can result in ''shell'' laboratory arrangements or otherwise be subject to patient and program abuse.

Comment: One commenter recognized the need to prohibit circumvention schemes by urban laboratories through the rural exemption, but thought that the proposed criteria may have a negative impact on a legitimate rural laboratory as follows: The criteria require laboratory testing referred by an investor physician to be performed on the premises or, if referred to another laboratory, that the testing be billed to Medicare directly by the laboratory performing the tests. This provision would prohibit rural laboratories from referring a limited number of tests to other laboratories and billing for the tests, in accordance with present statutory and regulatory requirements concerning shell laboratories.

One commenter indicated that, if a rural laboratory is not able to bill for reference work, it will be forced to collect patient information and forward it to the reference laboratory. This is necessary to enable the reference laboratory to bill Medicare. The rural laboratory will still be collecting the specimens for forwarding to the reference laboratory, but without compensation. The commenter also maintained that the rule will threaten the ability of small rural laboratories to maintain investment and employment while, on the other hand, the rule rewards large laboratories that already have the advantage of lobbying strength that can affect legislation. Also, the rule will not save the taxpayer any money, as good diagnostics for both treatment and preventive medicine are not a function of who bills Medicare for the tests.

This commenter suggested the following alternatives:

- Eliminate the condition that rural laboratories must perform in-house laboratory testing in order to bill Medicare directly.
- Revise the conditions to read: ''if all tests are not performed on the premises, 80 percent of referrals must be made by physicians who have office practices in rural areas and 67 percent of all tests must be performed on the premises, otherwise the laboratory performing the testing must bill the Medicare program directly.''

Response: We agree that the requirements we proposed for ownership in a rural laboratory are different from those found in the so called ''shell laboratory'' provision (section 1833(h)(5)(A)). Under the shell laboratory provision, payment may be made to a referring laboratory for the services of a reference laboratory in any of the following circumstances: the referring laboratory is located in, or is part of, a rural hospital; the referring laboratory is wholly owned by the reference laboratory; the referring laboratory wholly owns the reference laboratory; both the referring laboratory and the reference laboratory are wholly owned by the same entity; or not more than 30 percent of the clinical diagnostic laboratory tests for which the referring laboratory (other than a laboratory described in the ''wholly owned'' provision) receives requests for testing during the year in which the test is performed are performed by another laboratory. These provisions apply to the payment of Medicare-covered clinical diagnostic laboratory services generally. Section 1877 and these regulations contain additional specific requirements that apply to referrals for clinical laboratory services by physicians who have a financial relationship with the laboratory.

In the proposed rule, we stated that laboratory testing that is referred by a physician who has an ownership or investment interest in the rural laboratory must either be performed on the premises of the rural laboratory or, if not performed on the premises, the laboratory performing the testing must bill the Medicare program directly for the testing. Section 1877(d)(2) specifically provides the exception for referrals for clinical laboratory services if the laboratory furnishing the service is in a rural area. We do not believe the exception is satisfied if the rural laboratory in turn refers the work to a laboratory in a nonrural area.

In addition, we do not see this requirement as conflicting with the more general shell laboratory provision, because our requirement applies specifically to the testing ordered by a physician who has a financial relationship with the laboratory. Thus, all other testing referred to the rural laboratory would be subject to the more lenient provisions of section 1833(h)(5)(A) mentioned above. We continue to support this position. It is our firm belief that the Congress provided the rural provider exception in order that beneficiaries living in rural areas would have access to clinical laboratory services that might not be available without the financial investments of local physicians. Without the safeguards included in this regulation, we believe it would be possible to defeat the purpose of the exception.

c. Future Reclassification of Rural Areas

Comment: One commenter indicated that the final rule should provide that laboratories that currently qualify under the rural exception will not be disqualified in the future based on metropolitan statistical area (MSA) reclassification. This clarification will provide stability to legitimate rural laboratories and avoid future uncertainty and future ''fireside'' sales.

Response: We do not believe the language in section 1877(d)(2) is susceptible to the suggested ''clarification.'' The statute specifically requires that a rural provider be located in a rural area as defined in section 1886(d)(2)(D).

Thus, a provider must be located in such an area, even if the MSAs are at some point reclassified for prospective payment purposes. In addition, we do not believe we should provide an additional exception for a rural provider whose area has ceased to be rural, since we have no evidence that the exception would be free from all risk of program or patient abuse.

3. Hospitals Outside of Puerto Rico

The OBRA '93 amendments to section 1877 substantially changed the provisions that directly concern physician/hospital relationships. Listed below is a table explaining the provisions prior to OBRA '93 and after OBRA '93, as they are in effect until January 1995; the table also reflects amendments made by SSA '94.

Before OBRA '93	OBRA '93
Exceptions for Ownership/Investment and Compensation	
1877(b)(4) exception relating to hospital financial relationships (ownership/investment and compensation) unrelated to provision of laboratory services.	OBRA '93 omitted, but SSA '94 reinstated until 1/95. But see 1877(e)(4) below.
1877(d)(3) exception for hospital ownership	1877(d)(3) unchanged.
Exceptions for Compensation Arrangements	
1877(e)(2) exception for employment and service arrangements with hospitals.	Omitted by OBRA '93; SSA '94 reinstated until 1/1/95
	1877(e)(2) exception for bona fide employment only, with any employer
	1877(e)(3) exception for personal service arrangements with remuneration from any entity.
	1877(e)(4) exception for remuneration from a hospital to a physician if not related to provision of clinical laboratory services.
1877(e)(4) exception for physician recruitment by a hospital	Still present, as 1877(e)(5).
	1877(e)(7) exception for compensation between a group practice and a hospital for services furnished under an arrangement.

Generally, the prohibition in section 1877(a)(1) on physician referrals excepts physicians who furnish services in certain situations or settings described in section 1877(b) (for example, in-office or HMO settings). In addition, under section 1877(a)(2), a financial relationship with an entity is defined as an ownership or investment interest in the entity except for such interests described in sections 1877(c) and (d). A financial relationship is also defined as a compensation arrangement between a physician (or immediate family member) and an entity, except for the arrangements described in section 1877(e). Of these provisions, the following exceptions directly concern physician/hospital relationships if the hospital either is not located in Puerto Rico or is not a rural provider.

• Under section 1877(d)(3), an exception is provided for referrals for clinical laboratory services to be furnished by a hospital located outside of Puerto Rico, even if the referring physician (or immediate relative) has an ownership or investment interest in the hospital, provided the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself and not merely in a subdivision of the hospital.

• Under section 1877(e)(2), a physician who receives payment from any employer, including a hospital (or who has an immediate relative who receives such payment) will not be prohibited from making referrals to the hospital for clinical laboratory services on the basis of this payment if the employment of the physician or family member is bona fide and for identifiable services. In addition, the terms of the employment must be for fair market value with no ties to the volume or value of referrals, and be commercially reasonable. Finally, the arrangement must meet any additional requirements imposed by the Secretary.

• Under section 1877(e)(3), a physician who receives (or whose immediate family member receives) remuneration from any entity, including a hospital, under a personal service arrangement will not be prohibited, on the basis of this remuneration, from making referrals to the entity for clinical laboratory services if the arrangement meets the following conditions:

+ The arrangement is for at least 1 year, set out in writing, signed by the parties, and specifies the services covered.

+ The arrangement covers all of the services to be furnished by the physician (or immediate family member) to the entity.

+ The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement and the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value and, except in the case of certain physician incentive plans, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

+ The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

+ The arrangement meets any other requirements imposed by the Secretary.

• Under section 1877(e)(4), a physician who receives remuneration from a hospital will not be prohibited from making referrals to the hospital on the basis of that remuneration if the remuneration does not relate to the provision of clinical laboratory services.

• Under section 1877(e)(5), a physician who receives remuneration from a hospital that is intended to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the medical staff of the hospital will not be prohibited from making referrals to the hospital if the following conditions are met:

+ The physician is not required to refer patients to the hospital.

+ The amount of remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

+ The arrangement meets any other requirements imposed by the Secretary by regulation.

• Under section 1877(e)(7), certain group practices may have an arrangement with a hospital to furnish clinical laboratory services that are billed by the hospital. The physicians may make referrals to the hospital for the furnishing of clinical laboratory services, as long as the following conditions are met:

+ Services provided to a hospital inpatient are furnished under an arrangement under section 1861(b)(3).

+ The arrangement began before December 19, 1989, and has continued in effect without interruption since that date.

+ With respect to the clinical laboratory services covered under the arrangement, substantially all of these services furnished to patients of the

hospital are furnished by the group under the arrangement.

+ The arrangement is set out in writing, specifies the services to be provided, and the compensation for the services under the agreement.

+ The compensation paid over the term of the agreement is consistent with fair market value and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

+ The compensation provided is under an agreement that would be commercially reasonable even if no referrals were made to the entity.

+ The arrangement meets any other requirements imposed by the Secretary by regulation.

a. Joint Ventures Not Related to the Hospital Laboratory

Comment: One commenter suggested that the condition found in proposed § 411.357(b)(3)(ii) concerning ''ownership or investment in * * * a hospital that * * * does not relate (directly or indirectly) to the furnishing of clinical laboratory services'' could be construed as precluding a physician who has a financial interest in another hospital/physician joint venture that is unrelated to the clinical laboratory from referring to the hospital laboratory. This commenter recommended that the final rule clarify that physicians with financial interests in other hospital-physician joint ventures will not be precluded from making referrals to the hospital laboratory.

Response: The proposed provision that the commenter asked us to clarify was based on the predecessor provision of section 1877(b)(4), which excepted a physician's financial relationship (ownership/investment interest or compensation arrangement) with a hospital if the relationship did not relate to furnishing clinical laboratory services. This provision was eliminated from the statute by section 13562 of OBRA '93, but was reinstated until January 1, 1995 by section 152(c) of SSA '94. The amended section 1877 also contains, in paragraph (e)(4), a new provision which excepts remuneration from a hospital to a physician if the remuneration does not relate to the provision of clinical laboratory services. Section 1877(e)(4) is retroactively effective beginning January 1, 1992, and remains in effect after January 1, 1995.

As for joint ventures, an exception for an ownership or investment interest held *with* a hospital may not be necessary. That is because section 1877(a)(2) defines a prohibited financial relationship of a physician *with an entity* as an ownership or investment interest *in the entity*. In the case of a joint venture held with a hospital, if the physician has no ownership or investment interest *in* the hospital, a prohibition based on ownership would not apply at all. That is, even though a physician may own a venture with a hospital, as separate partners, that does not mean that the physician actually owns any part of the hospital.

To determine whether a physician has an ownership interest in a hospital, we must define what constitutes a ''hospital'' for purposes of section 1877. Under the Medicare statute, section 1861(e) defines a ''hospital'' as an institution, but we have never specifically defined what constitutes an ''institution.'' Although section 1861 dictates what services and functions a ''hospital'' must provide to qualify as one, it does not appear to mandate any requirements relating to a hospital's corporate structure.

Hospitals often are structured in complex configurations as the result of tax laws and in response to a variety of business concerns. These configurations make defining a ''hospital'' almost impossible to do on a case-by-case basis. As a result, we are establishing a test that we believe will be relatively easy to apply. For purposes of section 1877, we are defining a ''hospital'' as any separate legally-organized operating entity plus any subsidiary, related, or other entities that perform services for the hospital's patients and for which the hospital bills. A ''hospital'' does not include entities that perform services for hospital patients ''under arrangements'' with the hospital. We believe these arrangements, by their very nature, involve situations in which hospitals contract with outside entities because they cannot or do not wish to provide the services themselves.

For example, a hospital might be a parent corporation that provides administrative services but that furnishes patient care primarily through a variety of subsidiaries such as a home health agency, a laboratory, or a radiology unit, each of which is independently incorporated. If the hospital bills Medicare for services provided by a subsidiary, then we regard the subsidiary as part of the hospital. A physician, as a result of this structure, could own a part of the hospital if he or she owns some of the remaining interest in the laboratory or other subsidiary, even if the physician does not own any of the parent corporation.

If a physician owns part of the hospital by virtue of owning some portion of a separately incorporated subsidiary, then the physician's referrals to the hospital's laboratory could be prohibited (absent some exception). However, if the physician owns part of the hospital by virtue of owning some portion of a separate corporation that provides services other than clinical laboratory services, the exception in section 1877(b)(4) could apply until January 1, 1995. That is, the physician would have a financial relationship with the hospital (an ownership interest in the hospital) that does not relate to the provision of clinical laboratory services.

If, in contrast, a physician has an ownership interest in the hospital as a whole, we believe that this interest is indirectly related to the provision of clinical laboratory services. That is because, in most cases, a hospital's revenues will reflect the revenues earned by its clinical laboratory. It is for this reason that we included in proposed § 411.357(b)(3)(ii) the concept of ownership or investment interests that relate ''directly or indirectly'' to the furnishing of laboratory services.

Even if a physician has no ownership interest in the hospital (either in its operating entity or in a subsidiary), referrals to the hospital laboratory might still be prohibited, however, if the joint venture is structured so that there is some compensation passing between the hospital and the physician. If the hospital provides remuneration to the physician, that remuneration will result in prohibited referrals, unless an exception applies. Referrals would not be prohibited under section 1877(e)(4) and § 411.357(g) of this final rule if the remuneration is unrelated to the provision of clinical laboratory services; for example, the hospital and the physician might jointly own a free-standing CAT scanning facility. Any remuneration that flows from the hospital to the physician would be excepted if the remuneration relates only to the CAT scanning operation. This result, however, will change when the prohibition on referrals is extended to other designated health services beginning on January 1, 1995.

Comment: There were several other comments relating to the exceptions that apply to financial relationships between physicians and hospitals. Some commenters maintained that there is a conflict between the exception set forth in section 1877(b)(4) and the proposed regulatory exceptions. The argument is that this section of the law establishes a general exception for financial relationships with a hospital if the relationship does not relate to the provision of clinical laboratory services

but that a parallel exception was not included in § 411.355, the title of which is ''General exceptions to referral prohibitions related to ownership and compensation.'' Instead, the commenters pointed out, the proposed rule contains separate exceptions, one for ''ownership or investment interests'' and one for ''compensation arrangements.'' In the view of these commenters, these regulatory provisions are not consistent with section 1877(b)(4), and they recommended that the regulations be revised so that § 411.355 reflects the content of section 1877(b)(4).

Another commenter had several questions about proposed § 411.357(b)(3)(i) and what is meant by an ownership interest in a distinct part or department of a hospital. The commenter stated that most hospitals are incorporated entities, being either a for-profit or not-for-profit corporation and that parts or departments are assets of the incorporated entity and cannot be owned separately. This being the case, the commenter asked the following:

- How can a physician own an interest in a distinct part of a corporation or was the intention to refer to ownership of entities related to a hospital?
- Why should ownership in an entity related to a hospital cause referrals from a physician to be prohibited if the related entity is not a clinical laboratory (for example, a hospital owns 60 percent of a subsidiary that is not a clinical laboratory and the physician owns 40 percent).
- Why should the facts of this example result in a situation that is any more subject to abuse than one in which a physician has general ownership in the hospital and is authorized to perform patient care services at the hospital?

Response: The first set of commenters maintained that there was a conflict between the exception set forth in section 1877(b)(4) and the proposed regulatory exceptions. We believed that the combination of the provisions at § 411.357(b)(3)(ii) of the proposed rule and § 411.359(g) of the proposed rule effectively incorporated the section 1877(b)(4) provision. We had considered including the content of these two regulatory provisions under one provision in § 411.355, as was suggested in the comment, but that section of the regulation addresses services that can qualify for an exception, whereas section 1877(b)(4) addresses financial relationships that can qualify. Since under section 1877(a) all financial relationships are either ownership/investment interests or compensation arrangements, we included the section 1877(b)(4) exception under both § 411.357 (which applies to ownership/investment exceptions, and is now § 411.356) and § 411.359 (which applies to exceptions for compensation arrangements, and is now § 411.357).

We believe the commenters' dissatisfaction with our method for incorporating section 1877(b)(4) may stem from the way we drafted the provision in § 411.359(g). We now believe that this proposal deviates from the statute. We discuss this issue and our solution for it in our response to the next comment.

As a result of OBRA '93, as amended by SSA '94, the ownership/investment aspect of section 1877(b)(4) applies only until January 1, 1995. Some aspects of the compensation exception continue in effect, since OBRA '93 incorporated them into section 1877(e)(4).

The second comment asked, in regard to proposed § 411.357(b)(3)(i) and section 1877(d)(3), how a physician can own an interest in a distinct part of a corporation when hospitals are one incorporated entity. As we explained in an earlier response, we believe that a ''hospital'' can consist of any separate legally-organized operating entity plus a variety of subsidiary, related, or other entities if the hospital bills for the services furnished to its patients by those entities. In drafting section 1877(d)(3), Congress itself perceived that a hospital can consist of separately owned, subdivided parts and that a physician could own an interest in either the hospital itself or only in a subdivision. We are defining ''hospital'' for purposes of this regulation, to reflect this concept.

The commenter has also asked whether the intention of the exception in section 1877(d)(3) was to refer to ownership of entities related to a hospital. Although the statute does not explicitly say this, it does say that the exception will not apply if a physician's ownership interest is merely in a subdivision of the hospital, rather than in the hospital itself. We believe that a subdivision can be a related entity. We have interpreted such entities, in response to other comments, as parts of a hospital if the hospital bills for services furnished by these entities to hospital patients (excluding situations in which services are furnished for a hospital ''under arrangements''). A physician with an interest in a joint or related entity would not have an ownership interest in the hospital at all if the hospital did not bill for the services furnished by the joint or related entity.

The commenter has also asked why ownership in a related entity should cause referrals from a physician to be prohibited if the entity is not a clinical laboratory (for example, if the hospital owns 60 percent of a non-laboratory entity and the physician owns 40 percent). If the entity in this situation is part of the hospital, any referrals by the physician to the hospital laboratory would not qualify for the exception in section 1877(d)(3). To qualify for this exception, the physician's ownership interest must be in the hospital itself and not in a subdivision. However, the physician's referrals could qualify for the exception in section 1877(b)(4) which, until January 1, 1995, excludes any ownership interest in a hospital, provided the ownership interest does not relate to the provision of clinical laboratory services.

Finally, the commenter has asked why the facts in the example should be more subject to abuse than one in which a physician has a general ownership in the hospital and is authorized to perform patient care services there. Section 1877(d)(3) specifically requires that, to take advantage of this exception, a physician must have an ownership interest in the hospital itself, and not in a subdivision. We must reflect this requirement in the regulation, and have incorporated it into the final rule at § 411.356(b)(3). We have not broadened this exception to apply to any other ownership interest in a hospital because we have seen no evidence that such an expanded exception would be free of the risk of program or patient abuse.

Comment: There were two comments relating specifically to proposed § 411.359, which contains exceptions for certain compensation arrangements. One commenter asked under what authority we had limited the broad exception in section 1877(b)(4). Under that exception, the commenter pointed out, *any* financial relationship with a hospital is excepted (ownership/investment interest or compensation arrangement), as long as the relationship does not relate to the furnishing of clinical laboratory services. As such, the commenter questioned why this exception was not included under proposed § 411.355, which covers general exceptions that apply to both ownership/investment and compensation relationships. The commenter believed that, in covering section 1877(b)(4) under § 411.359(g), we had limited the exception so that it no longer constitutes the broad exception, for all financial relationships, included in the statute.

The commenter referred to the fact that the exception in § 411.359(g) is

entitled ''other arrangements with hospitals'' and indicated that the provision is drafted so that this exception applies to compensation arrangements between a hospital and a physician (or family member) other than those arrangements described in §§ 411.359 (a) through (d). (These arrangements in paragraphs (a) through (d) include rental of office space, employment and services arrangements with hospitals, physician recruitment, and isolated transactions. To qualify for these exceptions, physicians and entities must meet a variety of conditions.) The commenter pointed out that, under section 1877(b)(4), the only condition is that a financial relationship cannot be related to the furnishing of clinical laboratory services.

The commenter has read the proposed rule to mean that the exception in § 411.359(g) applies *only if* the compensation arrangement is not one of the ones described under paragraphs (a) through (d). Thus, for example, a hospital may have one or a variety of arrangements with a physician who is performing outpatient surgery on a patient at the hospital. These arrangements could include the rental of office space, employment or service arrangements, physician recruitment arrangements, or isolated transactions. The commenter believed that if a physician had one or more of these arrangements but could not meet the conditions to qualify for an exception, the exception in § 411.359(g) would automatically be foreclosed. That is, if the physician's financial arrangement was one already described in § 411.359 in paragraphs (a) through (d), then it could not be covered by paragraph (g), which applies only to financial arrangements other than those in paragraphs (a) through (d).

The commenter feared that the proposed rule could result in situations in which the hospital's laboratory would refuse to accept the physician's Medicare patient for laboratory work, with the result that the patient could not receive needed medical care at the hospital. The commenter questioned our authority to limit the statutory exception in section 1877(b)(4) and asked that we, at a minimum, add an exception for emergency laboratory work that would apply whenever, in the judgement of the physician, laboratory tests are needed quickly.

Another commenter recommended that the exception addressed in proposed § 411.359(g) be broadened to permit a direct or indirect financial relationship between a physician and a hospital or hospital affiliated organization or entity.

Response: In drafting § 411.359(g), we intended to cover any compensation arrangements that were not described in §§ 411.359 (a) through (d), including those that were the kinds of arrangements described in those provisions but that did not meet the conditions specified in them. We agree with the first commenter that the way we drafted § 411.359(g) is ambiguous and can cause confusion. As a result, we have made § 411.359(g) an independent exception, as it is in the statute.

We have also made several other changes to this provision to reflect amendments to the statute. As we have discussed in other responses, OBRA '93 eliminated section 1877(b)(4), which excepted any ownership/investment interest or compensation arrangement with a hospital that does not relate to the provision of laboratory services. The relationship could be between a physician and a hospital or an immediate family member and a hospital. SSA '94 reinstated section 1877(b)(4) until January 1, 1995. OBRA '93 also added paragraph (e)(4) to section 1877, retroactive to January 1, 1992. This new provision differs somewhat from paragraph (b)(4) in the sense that it retains only the compensation aspect of the exception. In addition, it applies only to remuneration from a hospital to a physician (not to a family member) if the remuneration does not relate to the furnishing of laboratory services.

The commenter also believed that we should provide an exception for referrals by physicians whenever, in the judgment of the referring physician, laboratory tests are needed quickly to treat a patient whose condition will worsen or be put at risk absent prompt laboratory results. We believe that section 1877 and this final regulation provide sufficient exceptions to ensure, in almost all cases, that patients should not be in the position of having their health threatened because of the general referral prohibition. In addition, the commenter's recommendation would give physicians total discretion that could be subject to abuse.

We do not agree with the suggestion that relates to broadening the exception in proposed § 411.359(g) so that it would apply to permit a direct or indirect financial relationship between a physician and a hospital affiliated organization or entity. The current authority in section 1877(e)(4) limits the exception to remuneration provided by a hospital, and not some other entity. We have interpreted the term ''hospital'' to include related or affiliated organizations or entities in situations in which the hospital bills for services provided to hospital patients by the organizations or entities (except when the services are provided ''under arrangements''). However, we do not believe that expanding the exception to other, non-hospital organizations or entities would necessarily be free of the risk of patient or program abuse.

Comment: One commenter asked that we explain what is meant by the phrase ''does not relate to the furnishing of clinical laboratory services,'' as used in proposed § 411.357(b)(3)(ii) and § 411.359(g). The commenter wanted to know whether a physician who is not authorized to perform patient care services at a for-profit hospital but who has an ownership interest in the hospital is considered to have a financial relationship that is related to the provision of laboratory services. The physician receives dividends based on the business profits earned by the hospital. These dividends may in part depend on the provision of laboratory services.

Response: The commenter has asked about a physician with an ownership interest in a hospital. The commenter has apparently correctly perceived that, because the physician is not authorized to provide patient care services in the hospital, the exception in section 1877(d)(3) and in proposed § 411.357(b)(3)(i) would not apply.

For purposes of the exception in section 1877(b)(4) and proposed § 411.357(b)(3)(ii), the commenter has asked whether the physician's ownership interest in the hospital relates (either directly or indirectly) to the furnishing of clinical laboratory services. We would consider the physician's ownership interest as related to the provision of clinical laboratory services. We base this conclusion on the fact that general ownership in a hospital includes an interest in the hospital laboratory. This exception could apply if the physician had an ownership interest in a subdivision of the hospital which did not provide clinical laboratory services. We would like to point out that, as the result of OBRA '93 (as amended by SSA '94), the exception in section 1877(b)(4) relating to ownership and investment interests is no longer in effect, beginning on January 1, 1995.

b. Ownership and Compensation

Comment: One commenter requested that the final rule clarify that a physician who meets the exception relating to an ownership or investment interest in § 411.357(b)(3) of the proposed rule not also be required to meet the exception relating to compensation arrangements in proposed

§ 411.359(g) in regard to arrangements that are incident to the physician's ownership. Examples of such arrangements are the initial offer to allow the physician to acquire the ownership interest, dividends paid to the physician as an owner, or the opportunity to enter into a stockholders agreement that would provide for the buyout of the physician's ownership on death, disability, retirement, etc., or that provides the hospital with a right of first refusal to buy the physician's ownership interest in a hospital.

Response: We believe that the commenter has asked about compensation arrangements that are inherent in certain ownership/investment situations for which there are exceptions under the proposed regulation. We believe that a return on equity (for example, dividends) that a physician gets as a consequence of being an owner is not considered a compensation arrangement.

We take this position because section 1877 is designed to prohibit referrals to an entity whenever a physician has a financial relationship with that entity. The purpose is to prevent physicians from realizing a financial gain or some other benefit from making those referrals. The Congress specifically defined ''financial relationship'' to include two distinct components: an ownership/investment interest and a compensation arrangement. By this, we believe the Congress meant to encompass two mutually exclusive concepts: (1) Investment/ownership interest and whatever potential compensation or value they have or may bring to the owner, and (2) all other arrangements that result in some compensation.

Since we believe that potential compensation from an ownership/investment interest is already factored into the investment/ownership exceptions, it would make little sense to review the resulting compensation against the exceptions for compensation arrangements. For example, it would make little sense to say that a physician can invest in publicly traded securities under the ownership/investment exception in section 1877(c), yet preclude the physician's referrals because the compensation he or she receives from these investments does not fall within any of the compensation exceptions. As a result, the prohibition on referrals should apply only when a physician has a compensation arrangement that results from something other than an excepted ownership or investment interest. It is to these compensation arrangements, which do not stem from an ownership or investment interest, that the compensation exceptions apply. Thus, we agree that a physician would not be required to qualify for both exceptions in order to refer laboratory tests to the laboratory in which he or she has an ownership interest.

G. Exceptions to the Referral Prohibition Related to Compensation Arrangements

1. Rental of Office Space

Section 411.359(a) of the proposed rule describes the exception under which the rental of office space does not constitute a financial relationship subject to the prohibition on referrals. The exception applies as long as payment made by a lessee to a lessor is made under the following conditions:

- There is a rental or lease agreement that meets the following requirements:
  + The agreement is set out in writing and is signed by the parties.
  + The agreement identifies the premises covered by the agreement and specifies the space dedicated for the use of the lessee.
  + The term of the agreement is at least 1 year.
  + If the agreement is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of the intervals, their precise length, and the exact rent for the intervals.
  + The agreement provides for payment on a periodic basis of an amount that is consistent with the fair market value of the rented or leased premises in arm's-length transactions.
  + The agreement provides for an amount of aggregate payments that does not vary (directly or indirectly) on the basis of the volume or value of any referrals generated between the parties.
  + The terms of the agreement would be considered to be commercially reasonable even if no referrals were made between the lessee and the lessor.
- If an interested investor (either a physician or immediate family member) has an ownership or investment interest in the rented or leased office space, the arrangement meets the following conditions:
  + The rented or leased office space is in the same building in which the physician's practice or the physician's group practice is located.
  + All of the requirements described in paragraphs (a)(1)(i) through (a)(1)(vii) of § 411.359 are met.

Section 1877(e)(1) as enacted by OBRA '89 was significantly changed by OBRA '93. Section 152(c) of SSA '94 amended the effective date provision for OBRA '93 so that the amendments to the rental exception are effective retroactively to January 1, 1992. The OBRA '93 provisions for the rental of office space provide that payments made by a lessee to a lessor for the use of a premises shall not be considered a compensation arrangement if—

- The lease is set out in writing, signed by the parties, and specifies the premises covered by the lease.
- The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if such payments do not exceed the lessee's pro rata share of expenses for such space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using such common areas.
- The lease provides for a term of rental or lease for at least 1 year.
- The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- The lease would be commercially reasonable even if no referrals were made between the parties, and
- The lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

Comment: A number of commenters raised questions about the meaning of the ''same building'' requirement in section 1877(e)(1)(B). Prior to OBRA '93, section 1877(e)(1)(B) stated that, ''in the case of rental or lease of office space in which a physician who is an interested investor (or an interested investor who is an immediate family member of the physician) has an ownership or investment interest, the office space is in the same building as the building in which the physician (or group practice of which the physician is a member) has a practice.'' Several commenters also questioned the meaning of the terms ''investor,'' ''interested investor,'' and ''disinterested investor'' in section 1877(h) (5) and (6).

Response: OBRA '93 amended section 1877(h) to eliminate the terms ''investor,'' ''interested investor,'' and ''disinterested investor.'' In addition, OBRA '93 eliminated the ''same building'' requirement in section 1877(e)(1)(B), effective January 1, 1995.

SSA '94 amended the OBRA '93 effective date provision so that the revised version of section 1877(e)(1) is retroactively effective to January 1, 1992. As a result, these terms are not reflected in this final rule.

2. Isolated Transactions

Under § 411.359(d) of the proposed rule, referrals by physicians involved in isolated financial transactions, such as the one-time sale of property, qualify for an exception if certain conditions are met and there is no other financial relationship between the entity and the physician for 1 year before and 1 year after the transaction.

Comment: Many commenters believed that the 1 year requirement creates substantial and unnecessary problems.

If a laboratory were to purchase assets from a physician on a one-time basis, it would not be able to accept future Medicare referrals from this physician if there were any previous relationship between the laboratory and the physician.

Response: We attempted in the proposed regulation to quantify and define an ''isolated transaction'' by adding the 1-year requirement. However, because commenters felt that this requirement creates substantial problems, we have decided to replace it with what we believe is a simpler and clearer standard. To define ''isolated,'' we have eliminated the requirement that there can be no financial relationship between the parties for 1 year before the transaction, and we have shortened the period after the transaction. We have replaced this with the requirement that there can be no other unexcepted financial relationship between the parties for 6 months after the ''isolated transaction.'' That is, if the two parties enter into a compensation arrangement within the 6-month period that qualifies for another exception, such as the employment or personal services exception, or if one of the parties qualifies for one of the ownership exceptions, the original transaction can still qualify as an ''isolated'' one.

We have also added a definition of ''transaction'' to make it clear that we regard an isolated transaction as one involving a single payment. If a financial relationship involves long term or installment payments (such as a mortgage), each payment constitutes a separate transaction, and would result in an ongoing financial relationship. (Individual payments between parties generally characterize a compensation arrangement. However, debt, as described in the statute in section 1877(a)(2), can constitute an ownership interest that continues to exist until the debt is paid off.)

3. Service Arrangements With Nonhospital Entities

Under proposed § 411.359(e), which reflects section 1877(e)(3) before it was amended by OBRA '93, referrals by a physician who has an arrangement to provide specific identifiable services to an entity other than a hospital would not be prohibited if the services are furnished—

- By the physician acting as the medical director or as a member of a medical advisory board of the entity in accordance with a Medicare requirement;
- As physicians' services to an individual receiving hospice care for which Medicare payment may only be made as hospice care; or
- As physicians' services to a nonprofit blood center.

The arrangement must satisfy certain requirements that also apply to employment and service arrangements with hospitals.

As discussed in section I.D.6.d. of this preamble, section 1877(e)(3) was amended by OBRA '93 and now provides that certain personal service arrangements with any entity will not be considered compensation arrangements for purposes of section 1877(a)(2)(B). This provision applies to remuneration paid by any entity to a physician, or to an immediate family member, for furnishing personal services. The exception applies if certain conditions are met. Finally, section 152(c) of SSA '94 amended section 13562(b)(2) of OBRA '93 (the effective date provision for OBRA '93) to create a new paragraph (D). This new effective date provision says that section 1877(e)(3), as amended by OBRA '93, is in effect beginning on January 1, 1992; however, until January 1, 1995, it does not apply to any arrangement that meets the requirements of section 1877(e)(2) or (e)(3) as they were in effect prior to the OBRA '93 amendments.

Comment: One commenter indicated that under the CLIA regulations (42 CFR part 493) laboratories must have physicians who act as laboratory directors, rather than medical directors. Thus, the commenter believed the regulations should be modified so that it is clear that a laboratory does not have a compensation arrangement if it pays a physician to act as the laboratory director of the entity.

Response: Under the revised provision in section 1877(e)(3), remuneration from an entity to a physician for the provision of the physician's personal services will not prohibit the physician from referring clinical laboratory services to the entity providing the following conditions are met:

- The arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement.
- The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity.
- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.
- The term of the arrangement is for at least 1 year.
- The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and except in the case of a physician incentive plan described in section 1877(e)(3)(B), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.
- The arrangement meets any other requirements the Secretary imposes by regulations as needed to protect against Medicare program or patient abuse.

Comment: One commenter indicated that there appear to be a number of relationships between clinical laboratories and physicians that are not specifically covered by proposed § 411.359 but would be protected by the fraud and abuse safe harbors. The commenter suggested that the final rule be expanded to specifically state that an arrangement would not violate the physician referral rule if it fits within a safe harbor under the fraud and abuse regulations.

Response: As mentioned in the preamble of the proposed rule and in the response to other comments, the anti-kickback and safe harbor provisions of the law and the section 1877 prohibition are intended to serve different purposes. The safe harbor provisions have been specifically designed to set forth those payment practices and business arrangements that will be protected from criminal prosecution and civil sanctions under the anti-kickback provisions of the statute. Conversely, section 1877 prohibits a physician's Medicare referrals for clinical laboratory services to entities with which the physician (or a family member) has a financial relationship when those referrals are not

specifically excepted under section 1877. Because of these distinctions, the provisions of the regulations implementing these laws will not exactly correspond. Additionally, we note that, under the amendments created by OBRA '93 (particularly in the new sections 1877(e)(2) and (e)(3)), many more relationships between physicians and laboratories are now excepted from the effects of the prohibition on referrals.

Comment: One commenter indicated that a justifiable distinction cannot be drawn between the employment of a physician (or family member) by a hospital, which in some cases would be excepted under § 411.359(b) of the proposed rule, and employment of a physician (or family member) by a nonhospital laboratory, which could not be excepted under proposed § 411.359.

Response: Section 1877(e)(2), as amended by OBRA '93, recognizes bona fide employment relationships without drawing a distinction between a hospital laboratory and nonhospital laboratories. Under the new provision, for purposes of section 1877, any amount paid by an employer to a physician (or an immediate family member of the physician) who has a bona fide employment relationship with the employer for the provision of services does not constitute compensation, providing the following conditions, set forth in § 411.357(c), are met:

- The employment is for identifiable services.
- The amount of the remuneration under the employment—
  + Is consistent with the fair market value of the services;
  + Is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician (although certain productivity bonuses are allowed); and
  + The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

H. Additional Exceptions

Under section 1877(b)(4), the Secretary is given the authority to define financial relationships beyond those specified in the law that could be exempt from the prohibition on referrals if the Secretary determines, and specifies in regulations, that they do not pose ''a risk of program or patient abuse.'' (Section 152(c) of SSA '94 amended the effective date provision for OBRA '93 to reinstate section 1877(b)(4), as it appeared prior to the enactment of OBRA '93, until January 1, 1995. The original version of (b)(4) provided an exception for financial relationships with a hospital which are unrelated to the provision of clinical laboratory services. As a result, we believe that there are two versions of section 1877(b)(4) in effect until January 1, 1995.) In the proposed rule, we requested recommendations about financial relationships that do not pose a risk of program or patient abuse. We received suggestions for additional exceptions, all of which are discussed below. In particular, the issue of shared laboratories was raised in the context of various business and practice arrangements, most often with respect to such shared arrangements between physicians.

1. Comments Relating to an Exception for Shared Laboratories

Comment: A few commenters strongly objected to the formulation of any special exception for shared laboratories. The commenters maintained that these arrangements could easily be used as a sham to circumvent the purposes of the law. They believed that a group of physician investors could set up a single laboratory to which they all refer testing. Each physician could then obtain his or her own CLIA number for the laboratory and bill separately for these services, thus making the detection of these schemes extremely difficult. Moreover, the commenters wrote that outside practitioners would also be allowed to refer their testing to any one of these physicians. Such an arrangement, in these commenters' view, is little more than a continuation of the physician-owned laboratory under a different name and is a way for physician-owners to circumvent the terms of section 1877.

Response: We share the concerns raised by these commenters, and we agree that a separate exception cannot be justified. CLIA certifies each laboratory by location. It does not certify individuals. Therefore, a laboratory that registers for CLIA will register once and receive one CLIA registration number. Each shared laboratory location is to have one CLIA certificate regardless of the number of physicians conducting or supervising testing in that laboratory, and only one registration and compliance fee and proficiency testing enrollment and survey is required. Testing performed in the physician's office that contains the shared laboratory may be included under the shared laboratory certificate. Physicians who perform laboratory testing in their own offices, in addition to performing tests in a shared laboratory, must have a separate certificate for their office laboratory.

As we understand it, there are a variety of circumstances that involve shared office space in general and shared laboratories in particular. Examples of shared laboratories range from laboratories shared by two or more solo practicing physicians to larger laboratories that are shared by hospitals, other health care facilities, and group practices. In effect, these commenters believed that to establish an exception for practicing physicians who share a laboratory would thwart the intent of the statute to end potential and actual overutilization of laboratory services.

In the example presented by the commenters, several physicians set up a laboratory separate from any of their practices, share in the costs of its operation, and bill individually for services furnished to their own patients. (The commenters also stated that physicians who are not owners refer patients for tests.) Since the physicians each appear to have an ownership or investment interest in the laboratory, they would be precluded from referring to the laboratory, unless they qualify for an exception.

It is not clear from the example, but if each physician does not have a practice in the same building as the laboratory and does not directly supervise the laboratory personnel who are performing the services for the physician's patients, the supervision and location requirements of the in-office ancillary services exception in section 1877(b)(2) would not be met. Furthermore, as discussed in greater detail in response to the next comment, we do not believe that it would be possible to develop an exception to accommodate these circumstances that would meet the statutory test contained in section 1877(b)(4); that is, that there be no risk of program or patient abuse.

Nonetheless, we want to clarify that the in-office ancillary exception could apply if each of the individual physicians involved separately met the supervision, location, and billing requirements of section 1877(b)(2). For example, physicians A, B, and C each have their own offices in the same building. Each physician directly supervises the laboratory technician when the technician is performing services for the physician. In addition, each physician bills for services furnished to his or her own patients. We also want to provide an example of a situation that would not qualify for the in-office exception. For example, ten individual physicians each have their own office on different floors in a building and the laboratory they share is

located in the basement of the building. The physicians do not directly supervise the laboratory technician when the technician is performing services for the physicians. In addition, the laboratory bills for services furnished to the patients of the physicians.

In the first example, as long as the requirements of section 1877(b)(2) and § 411.355(b) are met, it would not matter if the physicians pooled resources to cover the costs of the space occupied by the laboratory or for the cost of the equipment or overhead. We emphasize that the in-office ancillary services exception has been amended by OBRA '93, effective retroactively to January 1, 1992. Before this amendment, the services under this exception had to be furnished by the referring physician or by another physician in the same group practice. Alternatively, services could be furnished by employees of the referring physician or of the physician's group practice, provided the employees were ''personally supervised'' by the referring physician or another physician in the group practice. This requirement has been changed by OBRA '93 to eliminate the requirement that only a physician's or group practice's employees can furnish services. Also, the term ''personally supervised'' has been changed to require that a technician's or other individual's services be ''directly supervised'' by the referring physician or by another physician in the group practice.

For purposes of this exception, we are explicitly defining ''direct supervision'' using the longstanding Medicare definition of this term. Under this definition, the physician must be present in the office suite and be immediately available to provide assistance and direction throughout the time a technician is performing services. We believe it is appropriate for us to define this term in this final rule with comment period, rather than in a new proposed rule. We have several bases for this conclusion.

First, we believe that the Secretary's definition for this term is interpretive. Interpretive, nonsubstantive agency promulgations fall into the Administrative Procedure Act (APA) exception to notice and comment rulemaking. See 5 U.S.C. 553(b)(A).

In defining ''direct supervision,'' we are merely explicating the Congress' desires rather than adding substantive content of our own. That is, the definition is a clarification of what is implicitly in the statute. A rule that clarifies a statutory term is the classic example of an interpretive rule. Interpretive rules are those that merely clarify or explain existing law or regulations. They serve an advisory function, explaining the meaning given by the agency to a particular word or phrase in a statute or rule it administers.

The term ''direct supervision'' is a longstanding term of art with a very particular meaning in the Medicare program. It appears in section 2050.2 of the Medicare Carriers Manual, Part 3—Claims Processing, which describes services that are ''incident to'' a physician's professional services. This definition has appeared in the manual since the 1970's. It has, over the years, affected the many physicians who bill for services or supplies that are furnished as an integral, although incidental, part of a physician's personal professional services in the course of diagnosis or treatment of an injury or illness. The same definition appears in the regulations at § 410.32(a), which states that, in general, diagnostic x-ray tests are covered only if performed under the ''direct supervision'' of certain physicians or by certain radiology departments. Congress, in using this term of art, has adopted and ratified the Secretary's definition.

We believe that in changing ''personally supervised'' to the familiar ''directly supervised,'' Congress was intending to make clear that it wished to incorporate a concept that the agency and the provider community have long understood. For example, physicians are quite familiar with this term because they can only bill for nonphysician services that are ''incident to'' their own services if the nonphysician services are performed under ''direct supervision.'' As such, we have reiterated in this regulation our long-standing definition for this term. The definition is a clarification of what the Secretary believes ''direct supervision'' means and has always meant; it does not add to the statute any additional substantive requirements.

We are aware of only one paragraph of legislative history for OBRA '93 that attempts to explain the meaning of the term ''direct supervision.'' The Conference Report for OBRA '93 states that—

> [T]he conferees intend that the requirement for *direct supervision by a physician* would be met if the lab is in a physician's office which is personally supervised by a lab director, or a physician, even if the *physician is not always on site*. [Emphasis added.] H.R. Rep. No. 213, 103d Cong., 1st Sess. 810 (1993).

We believe that this explanation provides no insight into the Congress' purpose in using the term ''direct supervision.'' That is, it purports to explain what constitutes direct supervision, yet defines it by allowing a physician to ''directly supervise'' without even being present. This appears to us to be at total variance with the Medicare program's longstanding requirements for ''direct supervision,'' and with the statute, which specifically requires that the referring physician or another physician in the same group practice have *direct* involvement with individuals performing laboratory tests. In addition, the statute is very specific about who must directly supervise; it does not say that a laboratory director who is not a group member can provide this supervision instead of a solo or group practice physician.

Also, it appears to us that the legislative history is inconsistent. If ''direct supervision'' is interpreted to allow a laboratory director to supervise individuals who are furnishing services, this could have the effect of creating an exception for shared laboratories. The very same conference report points out that the House Energy and Commerce Committee introduced a provision that would have added an exception for shared laboratories. The conference agreement, however, specifically rejected this amendment. H.R. Rep. No. 213, 103d Cong., 1st Sess. 810 (1993).

Even without the ''interpretive'' exception, we believe that there would be good cause to waive notice and comment for this particular term. Title 5 U.S.C. 553(b)(B) authorizes agencies to dispense with certain procedures for rules when they find ''good cause'' to do so. Under section 553(b)(B), the requirements of notice and comment do not apply when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.''

We believe that waiting to define ''direct supervision'' in a future notice of proposed rulemaking would be both impracticable and contrary to the public interest. To begin with, some of the amendments added by OBRA '93 relating to clinical laboratories have a retroactive effective date. The provision containing the ''direct supervision'' requirement is effective retroactively back to January 1992. The retroactive effective date for some provisions relating to clinical laboratory services, but not others, demonstrates the Congress' desire to expedite their implementation. Although an expedited timeframe alone may not justify a ''good cause'' exception, we believe it is a crucial factor when considered in conjunction with the entire set of circumstances.

The in-office ancillary services provision establishes an exception to the referral prohibition that is critical to

the many solo and group practice physicians who wish to be excepted for referrals for their own in-office ancillary services. These physicians have had no way to be certain, from January 1992 until the publication date of this interim final rule, whether they qualify for the in-office ancillary services exception. They cannot know if they do until it is clear that they are ''directly supervising'' any individuals who perform laboratory tests. In short, a portion of the statute cannot be implemented without interpretation, although some form of ''supervision'' has been required since January 1992.

Defining ''direct supervision'' in this interim final rule avoids piecemeal promulgation of the statute for critical provisions such as this one. The in-office ancillary services exception is an important one that affects many physicians in a variety of situations, including those involved in shared laboratories. We have received a tremendous number of inquiries on how shared laboratories fit within the statutory scheme. We cannot provide a definitive answer to many of these inquiries until we define ''direct supervision.'' Without certainty, physicians and entities affected by this provision will continue to be confused about how to handle their highly complicated financial relationships. They may divest themselves unnecessarily of interests that we believe the Congress meant to excuse when it created the in-office ancillary exception.

Any uncertainty over the meaning of ''direct supervision'' could also damage our ability to enforce section 1877. If we take no action and delay enforcement of the referral prohibition because of uncertainty about the ''direct supervision'' requirement, we could be allowing over-utilization of services by physicians who have financial relationships with an entity and who continue to make prohibited referrals to that entity.

Finally, we are providing a comment period following publication of this interim final rule. We will carefully consider all comments we receive on the definition of ''direct supervision'' and publish our responses to these comments in a final rule.

The long-standing definition of ''direct supervision'' makes the proximity of the laboratory to each physician's office important. That is, in the first example, the laboratory must be situated in a way that each of the three physicians would be able to directly supervise the services of the individual performing the testing when the testing is being performed for the physician's own patients. This means that it is possible for a physician to have his or her office practice in a location separate from the laboratory as long as the laboratory is in the same building in which the physician practices and he or she fulfills the direct supervision requirement by being in the office suite when the tests are performed.

Finally, the exception in section 1877(d)(2) and § 411.356(b)(1) for clinical laboratory services furnished in a laboratory located in a rural area applies to shared laboratories. This exception, however, applies to referrals that would otherwise be prohibited only because of ownership or investment interests. The exception does not apply if the referring physician has a compensation arrangement with the rural laboratory. Therefore, if physicians share ownership in a laboratory located in a rural area but have no compensation arrangements with the laboratory (for example, remuneration between the physicians and laboratories other than return on investment), referrals by the physicians to the rural laboratory would not be prohibited provided the criteria mentioned above are met.

Comment: A majority of commenters regard the absence of a ''shared laboratory'' exception to be a serious oversight. These commenters indicated that shared clinical laboratories are very common, especially among younger physicians still building their solo practices and among providers in rural or medically underserved areas, whose populations could not otherwise support an independent laboratory testing facility. Other commenters indicated that an exception to permit physicians to make Medicare referrals to their shared laboratories would eliminate the discrimination that exists in the proposed regulations in favor of group practices and individually practicing physicians who can afford to purchase their own laboratory equipment solely for their own use. The commenters suggested that an exception could be added to permit referrals when all of the following factors are present:

- The shared arrangement involves a fixed and limited number of physician practices. The maximum may be specified by the Secretary.
- The arrangement involves only physicians who occupy the same office space or who practice in contiguous offices in the same building.
- The physicians in the arrangement refer only their own patients to their shared laboratory, which would not accept Medicare referrals from other physicians.
- The tests are done by the physicians' employees and are directly supervised by the physicians, or the physician personally performs the laboratory test for his or her own Medicare patients.
- No physician in the arrangement may be required to maintain a specific level or volume of laboratory referrals.
- The services are billed by one of the following:

  + The physician performing or supervising the service.

  + An entity that is wholly owned by the physicians who are parties to the shared office laboratory agreement.
- The shared-office must not loan funds or guarantee a loan for any physicians who share in the costs of the laboratory and who are in a position to refer to the laboratory.
- The agreement under which the shared-office laboratory operates does not contain ''noncompetition clauses'' that prevent physicians who share in the costs of the laboratory from investing in other laboratories.
- The shared-office laboratory must not furnish its items or services to referring physicians who have an ownership interest in the shared-office laboratory or share in the costs of the laboratory differently from other physicians. (By this, we believe the commenter meant that tests referred by owner physicians are not given priority.)
- Physicians who share in the costs of the shared-office laboratory must disclose their interest to their patients when ordering tests from the laboratory.
- Operation of the laboratory must be the joint responsibility of the physicians and/or practice groups with actual costs shared on a per test basis.
- Shared physician office laboratories must demonstrate that the laboratory simply passes actual costs through to the participating physicians and group practices with no accumulation or distributions of net earnings.

Response: As evidenced by the number of comments concerning this issue and the detail contained in suggestions for an exception, it is clear that there is great concern about this matter. Nonetheless, the Congress, while it was deliberating over the changes it would make in section 1877 by enacting OBRA '93, considered an exception for shared laboratory facilities but chose not to enact it. (See H.R. Rep. No. 213, 103d Cong., 1st Sess. 809–810 (1993)). The Secretary does have the authority to establish a shared laboratory exception if she determines that there would not be a risk of program or patient abuse.

Unfortunately, notwithstanding the arguments for establishing such an

exception, there is not sufficient basis in the rulemaking record to support an exception that meets the statutory standard. For that reason, we believe that Congress should provide further clarification or specific statutory authority in this area.

- The first suggestion made by the commenters was that a shared laboratory be limited to a fixed number of physicians. In our view, however, any attempt to select a number (three, five, ten, and so on) would be arbitrary. That is because we do not currently have data that would support making a distinction based on the number of physicians involved. We see no rational basis on which to establish or impose a limit.
- The second suggestion is to limit the exception to physicians who occupy the same office space or whose offices are contiguous in the same building. As explained in the response to the last comment, depending on how the physician's office space and the shared laboratory space are physically arranged, the in-office ancillary services exception provided in § 411.355(b) could apply. But we emphasize that the direct supervision and billing requirements must also be met.
- With respect to the remaining points, even if considered cumulatively, they do not clearly describe a situation in which there could be no program or patient abuse. Physicians could still have the opportunity to overutilize services with the possibility of profit that is inherent in any ownership arrangement. We are not suggesting that all physicians who might wish to participate in shared laboratory arrangements would overutilize laboratory tests. We do not believe, however, that there is a basis for concluding that the arrangements pose no risk of patient or program abuse.

Comment: One commenter indicated that, if the Secretary establishes an exception for shared laboratories, physicians involved in shared laboratory arrangements could be required to attest in writing that they meet the criteria required by the Secretary. This requirement would be like the one in the proposed regulation requiring that physicians attest in writing to their Medicare carrier that they meet the group practice exception.

Response: To clarify one point, we required only one attestation in the proposed rule; that is, that a group practice attest in writing, to the appropriate Medicare carrier, that the group complied with the standard we proposed to use to determine whether substantially all of the patient care services of group member physicians are furnished through the group as was required by section 1877(h)(4)(B) (now section 1877(h)(4)(A)(ii)). There are other standards that a group practice has to meet in order to qualify, but we did not propose that they be the subject of an attestation procedure.

In any case, as explained above, we do not believe that a separate exception for shared laboratories is justifiable.

Comment: One commenter suggested that multiple group practices within the same building be allowed to refer patients to one central laboratory that was created for the patients of the group practices.

Response: What is described here may be a laboratory owned by several group practices that does testing for patients of each group. In effect, the laboratory would be an independent entity that is shared by several group practices in the sense that it does business with each of its group practice owners. (A second possibility is that the laboratory is owned by one group to perform testing for its own patients but also accepts referrals from other groups or other outside sources. This latter situation is discussed elsewhere in this preamble.)

As we have explained in earlier responses to comments, we are not providing a general exception for shared laboratories such as the one described by the commenter. The physicians in the multiple group practices could refer to the laboratory, provided that each referral meets the requirements of the in-office ancillary services exception in section 1877(b)(2). This means that the services must be personally performed by or directly supervised by the referring physician or another member of that physician's own group practice and the services must be billed by the referring physician, the group practice, or an entity wholly owned by the group practice or referring physician.

There is no evidence from the commenter's description that the group physicians personally perform or directly supervise the laboratory services. Also, if this is the case, the group practices cannot individually bill for the services under section 1833(h)(5)(A), which generally allows payment only to the person or entity that performs or supervises the performance of clinical diagnostic laboratory tests. If the laboratory bills, the services will not meet the billing requirement in section 1877(b)(2).

2. Specialized Services Laboratory

Comment: One commenter requested an exception for referrals for ''specialized services.'' This exception would permit the establishment of laboratories by groups of individual practitioners within a common area of expertise.

The exception would apply when there is a public health need for specialized clinical services not readily available in a geographic region.

According to the commenter, general laboratories may lack the equipment or the expertise to meaningfully analyze samples from patients suffering from particular diseases. The commenter stated that the cost of specialized services could be lowered by making them readily available to patients who would otherwise incur unnecessary costs and delays because samples have to be shipped to laboratories not reasonably close to them. The commenter stated, as an example, that laboratories that usually handle normal blood specimens typically fail to calibrate their laboratory equipment for renal patients who express blood values that depart significantly from the norm. In the commenter's view, the technicians at general laboratories tend to be inexpert at processing these abnormal samples. In turn, this causes dialysis patients to incur unnecessary expense and endure needless delays and incorrect test results. The commenter also stated that laboratories that are not expert in evaluating renal blood samples tend not to report patient values, including cumulative historical laboratory results, to dialysis clinics in the same detailed manner as laboratories that specialize in renal patients.

Response: As mentioned previously, a physician's Medicare referrals to a laboratory owned by that physician will not be prohibited if the laboratory is located in a rural area (as defined in new § 411.356(b)(1)). Therefore, physicians with an ownership interest in a specialized laboratory that is located in a rural area are not prohibited because of that investment from referring Medicare patients to the laboratory. We believe that it is likely to be in rural areas that specialized equipment or technical expertise would be in short supply.

Furthermore, we believe the CLIA certification that is now required for any laboratory that performs tests on human specimens will tend to induce those laboratories that fail to calibrate their equipment or operate in other ineffectual ways to improve their performance or risk going out of business. For example, under CLIA, laboratories are subject to proficiency testing and personnel requirements. Failure to comply with accepted standards can result in serious sanctions. Thus, we do not agree that a special exception is warranted because

some laboratories may not properly conduct tests.

3. Laboratories Shared With Hospitals

Comment: One commenter requested that we create an exception for a shared laboratory facility owned by an organization or hospital that is exempt from taxation under section 501(c)(3) of the Internal Revenue Code if the laboratory is used in common under a written agreement with a group practice and if the group practice constitutes all or substantially all of the staff of the organization or hospital. The commenter stated that the requirement that the entity that owns the laboratory be tax exempt under section 501(c)(3) of the Internal Revenue Code provides significant protection against patient and program abuse. (To qualify for and maintain tax-exempt status, an organization must be a corporation, or a community chest, fund, or foundation, organized and operated exclusively for a community purpose such as for religious, charitable, scientific, public safety, literary, or educational purposes. No part of the net earnings of the organization can inure to the benefit of any private shareholder or other individual. Failure to meet these requirements, or failure to continuously maintain them, results in the denial or loss of tax-exempt status.)

The commenter believed that the conditions associated with tax-exempt status would prevent physicians from having an ownership interest in the laboratory from which they could receive financial benefits in the form of dividends or other distribution of earnings, as a result of their referrals. Consequently, there would be no incentive to order an excessive number of clinical laboratory tests. The commenter pointed out that payment for unreasonable or excessive compensation would also be prohibited by the restriction on private inurement.

Response: It is not clear from this comment exactly what the financial relationship is between the tax-exempt hospital/organization and the group practice physicians. We will first assume that it is the hospital or organization only that owns the laboratory and the physicians receive compensation from the hospital/organization for providing staff services. This relationship will not prohibit referrals to the hospital's laboratory provided the compensation meets the requirements of one of the exceptions in section 1877. For example, section 1877(e)(2) (for bona fide employment relationships with an entity) or (e)(3) (for personal service arrangements with an entity) could apply. An additional exception appears in section 1877(e)(7), which exempts certain group practice arrangements with a hospital when a group practice provides services for which the hospital bills.

If, on the other hand, the group practice physicians have an ownership interest in the laboratory, they would be referring to a laboratory in which they have a financial interest under section 1877(a)(2), even if they do not receive dividends or earnings. The physicians could refer to their own laboratory, provided they meet the in-office ancillary services exception in section 1877(b)(2) and § 411.355(b) of this regulation. If the laboratory is rural, then the ownership relationship would be exempt under section 1877(d)(2). If the physicians have an ownership interest in a tax-exempt hospital itself, their relationship could be exempt under several hospital-specific exceptions.

Because there are a number of exceptions available for situations involving compensation between a hospital or other organization and a physician, or for ownership in a hospital, we believe that a specific blanket exception for laboratory facilities associated with a tax-exempt organization or hospital would be unnecessary. Also, we are not convinced that such an exception would be free from any risk of patient or program abuse. For example, a non-profit or tax-exempt organization can own a for-profit laboratory entity. Without further details and evidence, we would not grant such an exception.

Comment: One commenter indicated that an exception should be added for referrals to a laboratory facility that is shared by a hospital and a clinic. The commenter provided the following information. The clinic is a group practice. The shared laboratory is located on hospital premises, and the hospital owns the laboratory space. The clinic leases space from the hospital in an amount proportional to testing on the clinic's patients. Clinic staff manage the laboratory, and the clinic employs all the laboratory personnel. The clinic and hospital each own some of the laboratory equipment. As such, each entity essentially leases from the other entity the equipment needed to perform testing on its own patients. The laboratory is not a separate legal entity, but simply an arrangement that permits the clinic and hospital to work together. The parties entered into this arrangement in 1973 and it has been in effect since that time. Each party is responsible for billing and collecting fees related to laboratory services provided to its respective patients. The agreement provides that the clinic and hospital would coordinate management, planning, budgeting, and accounting for the laboratory services. The commenter indicated that an exception should be allowed for referrals to a laboratory facility that is shared by a hospital and a clinic (group practice) where the parties divide expenses on a basis that reasonably approximates the costs associated with the tests performed for each party's patients and each party bills for and retains revenues associated with the testing of its own patients.

Response: The commenter has asked for a specific exception for arrangements in which a laboratory facility is shared by a hospital and a group practice clinic. The commenter has described an arrangement which involves a variety of ownership and compensation arrangements, each of which could cause the group practice physicians' referrals to be prohibited. However, as a result of the additional exceptions included in section 1877 by OBRA '93, we believe that most of the relationships described by the commenter could be excepted. As such, a separate exception would be unnecessary.

The commenter first describes several compensation arrangements between the hospital and the group practice. The group practice rents the laboratory space and some equipment from the hospital. (The laboratory is not a separate legal entity and is located on the hospital's premises, so we assume it is part of the hospital.) The hospital, in turn, rents some of the equipment from the group practice. These arrangements should not preclude the physicians' referrals if they meet the exceptions in section 1877(e)(1) (A) and (B), which exempt rental arrangements provided certain conditions are met.

The group practice also provides certain services to the hospital by managing the laboratory and employing the staff. We assume that the group practice is receiving some compensation, in some form, from the hospital for these services. This compensation would not trigger the referral prohibition if the arrangement meets the requirements in the bona fide employment exception in section 1877(e)(2) or qualifies for the exception for personal services arrangements in (e)(3). Alternatively, the relationship might be exempted under the exception in section 1877(e)(7) for certain group practice arrangements with a hospital under which the group provides clinical laboratory services which are billed by the hospital. In this case, the group practice appears to provide most, if not all, of the actual laboratory services while the hospital apparently bills for

its own patients. To qualify for this exception, the group must meet the definition of a group practice in section 1877(h)(4) and meet the requirements under section 1877(e)(7).

Finally, there are certain indications that the group practice may have some form of ownership interest in the laboratory entity (although it may not be a separate legal entity). The group pays rent for the space, manages the laboratory, employs all of the laboratory staff, owns some of the equipment, bills for its own patients, and retains the revenues associated with the testing of its own patients. In order for the group practice to refer to its own laboratory, it must qualify as a group practice under the definition in section 1877(h)(4), and meet the requirements of the in-office ancillary services exception in section 1877(b)(2).

Comment: Several commenters indicated that a number of group practices and the hospitals with which they are affiliated have for many years operated a laboratory facility that serves both hospital patients and the group practice's office patients. Under the terms of the agreement between the group and the hospital, the laboratory is operated under a shared services agreement, rather than as a true joint venture or under an ''under arrangement'' contract. The revenues, costs, profits, and losses resulting from services to hospital patients are attributed to the hospital and the revenues, costs, profits, and losses resulting from services provided to the group practice's office patients are attributed to the group practice. The commenters recommended a new exception that would be limited to teaching hospitals and would apply to clinical laboratory services furnished by a laboratory that is—

- Owned or operated by an organization or hospital that participates in an approved medical training program; and
- Used in common under a written arrangement with a group practice whose physician members constitute all or substantially all of the active medical and teaching staff of the organization or hospital.

Response: This comment is very similar to the previous comment. That is, it involves an arrangement between a hospital or organization and a group practice to share a laboratory facility. The commenters, however, do not address the specifics of the arrangement, so we cannot tell exactly how the situation will be affected by section 1877. In addition, it is not clear why the commenters limited their recommendation for a new exception to just arrangements between teaching hospitals and group practices. However, as we pointed out in our response to the last comment, we believe that a new exception is unnecessary after OBRA '93 for most situations in which hospitals and other organizations share their laboratories with physicians.

In the commenter's example, for instance, the group practice physicians constitute all or substantially all of the active medical and teaching staff of the hospital or organization. The compensation that these physicians receive from the hospital or organization for their services should not prevent the physicians from referring to the hospital's laboratory, provided the arrangement meets the requirements under section 1877(e)(2) (for bona fide employment relationships) or (e)(3) (for personal services arrangements). The group practice physicians also appear to have some ownership interest in the laboratory, since they refer their own office patients there and the revenues, costs, profits, and losses of the group's office patients are attributed to the group. The group practice physicians can refer their own patients to each other, provided they meet the requirements of the in-office ancillary services exception in section 1877(b)(2).

Comment: One commenter indicated that there are large multi-specialty group practices that own clinics located adjacent to inpatient hospitals and the clinics share certain ancillary facilities, including laboratories, with the hospitals. In some cases, the ancillary services building literally becomes the bridge between the clinic and the hospital, so that a hospital patient enters the ancillary facility from the hospital, and a clinic patient enters the same facility from the clinic. Such a facility would be under the common control of both the clinic and the hospital, and both entities would share in the cost of personnel, space, equipment, supplies, and other operating expenses. The commenter questioned whether the physician group is entitled to treat such a shared facility as ''in-office.'' The commenter believed that if the services furnished at the facility do not qualify for the in-office ancillary exception, the physician group's referrals for those services would be prohibited since the cost sharing agreement between the hospital and clinic would constitute a compensation arrangement under the statute. The commenter requested that we provide an additional exception to accommodate arrangements of this nature that meet all of the following conditions:

- The shared laboratory facility, the group practice, and hospital (or other entity) are part of the same medical center campus.
- The costs of operation of the shared facility are shared on the basis of utilization originating from each part, so that each party pays only its own costs, and does not subsidize the provision of laboratory services to the other.
- The creation or continuation of such a shared facility arrangement is not conditional or otherwise related to the volume or value of referrals of patients between the clinic and hospital (or other entity) for other, nonlaboratory, covered Medicare services.

Response: The comments we have received on the issue of hospitals or similar organizations which share laboratories with group practices have revealed to us the complexity of many of the financial relationships involved in these arrangements. In some situations, one or both parties actually own the physical facility and/or its equipment, one party may pay rent to the other, and each party may provide the other with certain services both in the laboratory and in a practice context. It is impossible for us to analyze each and every configuration. However, as we pointed out in earlier responses on this issue, OBRA '93 has created additional exceptions which should address many of the interrelationships involved in these situations. We encourage hospitals and other organizations to analyze their own particular circumstances in light of these exceptions.

In regard to the particular situation raised by this commenter, the commenter describes a situation in which a laboratory is under the common control of both a group practice clinic and a hospital, each of which share in the cost of personnel, space, equipment, supplies, and other operating expenses. The commenter appeared to be concerned, primarily, about whether the in-office ancillary services exception would apply to services furnished in the laboratory for the patients of the group practice. The commenter provided few other details about ownership of the hospital or laboratory or whether there is any compensation passing between these parties.

The in-office ancillary services exception in section 1877(b)(2) does not appear to dictate any particular ownership arrangements between group practice physicians and the laboratory in which the services are provided. We believe that the group practice can take advantage of this exception and that members can refer to each other in the laboratory provided that the group meets the definition of a ''group practice'' under section 1877(h)(4) and

meets the requirements in section 1877(b)(2). Under section 1877(b)(2), the services must be furnished by the referring physician or a group member or must be directly supervised by a group practice member. In addition, the services must be billed by the referring physician, the group practice, or an entity wholly owned by the group practice.

Comment: One other commenter indicated that, if an exception is provided for contracts for services provided ''under arrangements'' as described in section 1861(w), the language should be broad and not limited only to those circumstances in which the arrangement between the parties meets the safe harbor for personal services and management contracts provided for in the anti-kickback rules (42 CFR part 1001). According to this commenter, this limitation would pose several problems. First, the personal services and management contracts safe harbor would require that the aggregate amount of compensation be set in advance and not vary based on the volume or value of tests performed. This would mean that the parties would have to establish in advance a flat yearly fee for laboratory services. Even a fee schedule would not qualify for the safe harbor. A flat aggregate fee arrangement would be of concern to the hospital because it would place the group practice physicians at risk for the provision of clinical laboratory services that are the hospital's obligation. Under this arrangement, the physicians would have a financial incentive to order too few laboratory services for hospital inpatients and outpatients in order to make the arrangement as profitable as possible. To ensure that hospital patients receive optimum quality health care services, the hospital would not want the physicians to have a financial disincentive to order medically necessary laboratory services. The hospital would also be concerned that this contractual disincentive may have liability implications for the hospital in the event of a misdiagnosis of a hospitalized patient allegedly because the appropriate diagnostic testing was not ordered.

The safe harbor for personal services and management contracts also requires that contracts for less than full-time services be specific about the frequency and timing of the services being furnished. This commenter believed that a hospital in this situation must clearly expect that the group practice laboratory will furnish services for the hospital on an as needed basis when the patient and the patient's attending physician require the laboratory service for appropriate diagnosis. Thus, the commenter concluded that this safe harbor criterion also could not be met.

Response: The commenter has described a situation in which group practice physicians both order and provide laboratory services to hospital inpatients and outpatients under an arrangement. We believe the commenter is correct in concluding that the section 1877 prohibition applies to both Part A inpatient hospital services as well as to Part B services.

The definition of ''referral'' found in section 1877(h)(5)(A) applies, by its terms, to items or services for which payment may be made under Part B of the program. Section 1877(h)(5)(A) is entitled ''Physicians' Services,'' which are separate from inpatient hospital services and are always covered under Part B. Section 1877(h)(5)(B), on the other hand, covers ''Other Items,'' and is not limited to Part B items and services. This provision states that, except for specific exceptions listed in (h)(5)(C), ''the request or establishment of a plan of care by a physician'' that includes clinical laboratory services constitutes a ''referral'' by a ''referring physician.'' We believe this provision is difficult to decipher. Nonetheless, it appears to contemplate that physicians have made a ''referral'' in either a Part A or Part B context if they establish a plan of care for an individual that includes clinical laboratory services.

In the ''inpatient hospital'' context, we believe that most patients will receive clinical laboratory services as part of their ''plan of care.'' We consider that anytime a physician orders anything, it is ''pursuant to a plan of care'' on the physician's part, even if not formally called that. In addition, we believe that the Congress fully intended to encompass Part A inpatient hospital services within the section 1877 referral prohibition. One of the designated health services that has been added to the prohibition effective January 1, 1995 (by section 1877(h)(6)(K)) is ''*inpatient* and outpatient hospital services.''

The commenter has asked about a specific exception for services furnished under arrangements. OBRA '93 amended section 1877 to establish such an exception in new paragraph (e)(7). This provision creates a limited exception for compensation that derives from an arrangement between a hospital and a group under which services are furnished by the group but are billed by the hospital. The provision specifies, in (e)(7)(A)(i) that, with respect to services furnished to an inpatient of a hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3). Section 1861(b)(3) defines what constitutes ''inpatient hospital services,'' and specifically includes certain services furnished to inpatients ''under arrangements.'' Among other requirements in section 1877(e)(7), the arrangement must have begun before December 19, 1989, and have continued in effect without interruption since that date. Also, the compensation paid over the term of the agreement must be consistent with fair market value and the compensation *per unit* of services must be fixed in advance and not take into account the volume or value of referrals. Therefore, this exception does not present the ''aggregate compensation'' problem discussed in the comment. Also, there are no additional requirements for details about the frequency or timing of services furnished under a less than full-time service arrangement.

In response to the commenter's concern about the safe harbor for personal services and management contracts, we caution that the anti-kickback safe harbor regulations implement different provisions of the Act than are implemented by these regulations. Therefore, physicians and laboratory entities are obligated to consider the safe harbor requirements separately from the requirements of this rule.

4. Rental of Laboratory Equipment

Comment: One commenter stated that laboratories often rent a variety of equipment to physicians that they need in connection with their practices. For example, a physician may want to rent a blood analyzer in order to perform simple laboratory tests in his or her office. Since laboratories often have extra equipment they rent, the laboratory that the physician uses for his or her reference work will likely be the laboratory from which the physician rents equipment. Laboratories typically charge some rental fee for this equipment if the equipment is not an integral part of the laboratory services furnished. These arrangements could, however, be considered a compensation arrangement that could jeopardize the physician's referrals to the laboratory. The commenter believed that, if the equipment is leased at fair market value and meets other requirements comparable to those set out in the provision related to the lease of office space, there is little risk of patient or program abuse. Thus, this commenter recommended that an additional exception be created for referrals by a physician who has a compensation arrangement with a laboratory through

an agreement under which the physician leases or has a role in leasing equipment from or to a laboratory.

Response: We agree with the commenter that, if a physician who is leasing equipment from a laboratory under controlled circumstances refers to that laboratory, this should not lead to program or patient abuse. Section 1877(e)(1)(B), which was added by OBRA '93 retroactive to January 1, 1992, excepts from ''compensation arrangements'' payments made by a lessee of equipment to the lessor for the use of the equipment if certain conditions (discussed earlier in this preamble at section I.D.7.b.) are met. These conditions are specified in § 411.357(b) of this rule.

5. Group Practice Affiliated Property Companies

In the impact analysis of the proposed rule (57 FR 8601), we discussed group practices with affiliated property companies that are owned by members of the group practice and that lease facilities or equipment to the group. We stated that the group practice would need to restructure if it wanted to continue to make Medicare referrals for clinical laboratory services. Technically, we regarded the lease of equipment by the property company to the group practice that operates a clinical laboratory as a compensation arrangement for which an exception was not provided in the proposed rule. In these cases, it was indicated that the prohibition on referrals would apply, which would require the group physicians to either purchase the equipment from the property company or divest their interests in the laboratory if they intended to continue to make Medicare referrals for clinical laboratory services.

Comment: According to one commenter, in some group practices, affiliated property companies serve as the vehicle for the retirement system for the equity partners in the group practice; that is, as vehicles for creating retirement income. This commenter recommended that we provide an exception for group practices that have affiliated property companies under circumstances in which there is no potential or incentive for program or patient abuse.

Response: What this commenter is concerned about is that the compensation arrangement between the affiliated property company and the group practice might prohibit referrals by the physicians of the group practice to their own in-office laboratory. In this situation, one or more of the group practice physicians who own the property company receive remuneration from the group practice. In the impact analysis of the proposed rule (57 FR 8601), we indicated that a group practice probably would have to divest its interest in an affiliated property company if it intended to refer Medicare patients to its in-office laboratory. After reconsidering the matter, however, we do not believe that our initial interpretation was correct.

Section 1877(a)(1) of the Act prohibits a physician from making referrals to an entity that furnishes clinical laboratory services if the physician or immediate family member has a financial relationship with that entity. In the situation described by the commenter, the group practice physicians appear to have a financial relationship with the affiliated property company which rents equipment to their laboratory, in the form of an ownership interest. We also regarded as a compensation arrangement the payments which the group practice makes to the affiliated property company for renting the equipment. However, the physicians in this case do not have these financial relationships with an entity that furnishes clinical laboratory services; their relationships are with an entity that only rents equipment to the group practice. As a result, these relationships with the affiliated property company should not affect the physicians' ability to refer to their own laboratory.

Instead, the group practice physicians' referrals could be prohibited because they are referring to a laboratory that they own. Section 1877(b)(2) provides an exception for group practices which refer Medicare patients to their own laboratory for in-office ancillary services. These services must be furnished personally by a member of the group practice or an individual who is directly supervised by a member of the group practice, provided these services are furnished in the building where the group practice has its office or a building that is used by the group practice for furnishing some or all of the group's clinical laboratory services. This provision also has certain billing requirements. The conditions in this exception do not place limitations on the origin of the laboratory equipment that is used by the group practice.

Thus, we have determined that, if the in-office laboratory services are furnished in the manner described by section 1877(b)(2) and § 411.355(b), the nature of the physician's financial relationship with the in-office laboratory is irrelevant. As a result, we do not believe that an additional exception is necessary.

6. Faculty Practice Plan Exception

Comment: Several commenters suggested that a separate exception be developed to treat faculty practice plans associated with accredited medical schools as a separate and distinct type of group practice. These commenters indicated that it is not uncommon in a faculty practice plan environment for the physicians to receive their compensation from one entity (the medical school, for example). However, they may conduct their practice through a separate entity that might be a professional corporation, partnership, or simply a contractually organized billing service. In addition they may order their laboratory work from one or more related entities (for example, the teaching hospital, the university's research laboratory for highly specialized testing, in-office laboratories within faculty departments that may or may not be incorporated as professional corporations, etc.). Since there is no consistent organizational arrangement that characterizes a faculty practice plan, these commenters requested that we develop a separate provision that would treat faculty practice plans associated with accredited medical schools as a separate and distinct type of group practice. They have suggested that the definition of a group practice and the separate requirements of the in-office ancillary exception be applied at the level of the umbrella organization. That is, they believed each legal entity within the same academic setting should not be required to satisfy these provisions. In this manner, any physician who is a staff member of the umbrella organization would be permitted to refer Medicare patients to laboratories that are owned or operated by the umbrella organization.

Response: We believe that the amendments made by OBRA '93 make an additional exception unnecessary. We acknowledge that faculty practice plan physicians may be associated with many organizations in an academic setting, in terms of receiving compensation, furnishing patient care, teaching, and doing research. For example, the medical school may pay the plan to teach residents or care for patients. Even though faculty practice plans may operate in a variety of arrangements, the common theme appears to involve physicians or groups of physicians who are compensated by some part of an academic center for providing a variety of services, and who are concerned about whether they can refer patients to laboratories that belong to the academic center.

If the physicians in the plan are directly employed by the academic center, then their referrals should not be prohibited if the employment meets the standards in section 1877(e)(2) and § 411.357(c). If, alternatively, the physicians or group practice members provide services to the academic center under contract, the personal services provided by these physicians would not be compensation if the arrangement meets the requirements in section 1877(e)(3) and § 411.357(d). In short, we cannot see why a separate exception would be necessary.

Comment: One commenter indicated that, in general, faculty practice plans fall under one of three organizational structures, as explained below:

- A single entity: Many faculty practice plans are organized as a single legal entity that submits a single bill for all physician services across specialties using one common Medicare provider number and, thus, clearly meeting the statutory billing requirement for a group practice.
- Multiple entities by specialty, each billing by its own group provider number: Other faculty practice plans within medical schools and teaching hospitals are organized as multiple legal entities, usually professional corporations established by specialty, that submit multiple bills using a provider number for the respective specialty group.
- Multiple entities by specialty, billing by individual physician provider numbers: Still other faculty practice plans are organized by groups but will submit multiple bills for service by specialty, using individual physician provider numbers.

The commenter recommended, therefore, that the final regulations recognize that a variety of faculty practice plan structures associated with a medical school or teaching hospital exist and should be able to qualify for the in-office ancillary services exception at the level of the umbrella organization. The commenter recommended that we not apply the criteria separately to each legal entity within the same academic setting.

Within an academic setting, according to another commenter, physicians may receive compensation from a variety of entities. They may order their laboratory work from one or more of these entities, such as a teaching hospital, a research laboratory for highly specialized testing, or in-office laboratories within faculty departments. Since there are often indirect financial relationships between and among the various entities within an academic setting, the law appears to prohibit referrals by faculty physicians between and among these entities. The research laboratory may provide a unique situation because, as the commenter pointed out, it generally performs a highly specialized range of laboratory tests that are not available elsewhere. Therefore, the commenter urged us to craft an exception in the final rule that allows these and similar nonabusive arrangements to continue in the academic setting.

Response: We believe that as long as the faculty practice physicians receive remuneration from the academic institution for their bona fide employment or under personal service arrangements that meet the criteria in sections 1877(e)(2) and (e)(3), the physicians should not be prohibited from making referrals to laboratories that are owned by the academic institution.

7. Special Exception for Group Practices

Comment: We stated in our proposed rule that within the definition of ''group practice'' substantially all (at least 85 percent) of the patient care services of group practice physicians must be furnished through the group and be billed in the name of the group. Further, amounts received for those services must be treated as receipts of the group. One commenter stated that there are situations in which group practices will be unable to meet the ''substantially all'' requirements of section 1877(h)(4), or whatever percentage of patient care services is adopted in the final regulations. The commenter offered the example of 15 independently practicing physicians who have primary offices in one part of a city and establish a group practice clinic in a medically underserved area in the same city. Each physician spends 1 day a week at the clinic. In this case, only 20 percent of the services of the physicians in the group would be furnished through the group. This would be insufficient to meet the requirement of proposed § 411.351 that at least 85 percent of the aggregate services furnished by all physician members be furnished through the group practice.

The commenter recommended that an exception be added to the regulations that would allow group practices in medically underserved urban areas to furnish clinical laboratory services without being required to meet the ''substantially all'' requirement. In this commenter's view, this exception would tend to increase the availability of medical care in those urban areas currently deprived of adequate medical services without creating patient or program abuse.

Response: We note that the Congress has determined that there is a shortage of adequate medical care in locations designated as health professional shortage areas (HPSAs) under section 332(a)(1)(A) of the Public Health Service Act. In order to avoid discouraging group practice physicians from providing services in HPSAs, we are redefining the ''substantially all'' criteria in the definition of a group practice in § 411.351 in two ways. First, we are excluding from the ''substantially all'' test group practices that are located only in certain HPSAs. We have defined the term HPSA in reference to the definition of the term under the Public Health Service Act. Section 332(a)(1)(A) of the Public Health Service Act defines the term HPSA to include so-called ''geographic HPSAs,'' that is, ''an area in an urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services) which the Secretary determines has a health manpower shortage and which is not reasonably accessible to an adequately served area.''

The Secretary has established criteria for designating areas having shortages of a number of types of health professionals, including primary medical care (which includes general or family practice, general internal medicine, pediatrics and OB/GYN), dental, mental health, vision care, podiatric, and pharmacy professionals. For purposes of this regulation, if an area is a primary care HPSA, any group practice located solely in that HPSA (regardless of whether it provides services of the type classified as primary medical care) will be exempt from the ''substantially all'' test. Since HPSAs do not exist for a number of specialty areas (for example, oncology, dermatology, neurology), if an area is a primary medical care HPSA, we believe that it is likely that there is a shortage of other types of professionals. Therefore, any group practices that are located solely in such an area and provide services of any type will be exempt from the ''substantially all'' calculation.

In addition, if an area has been designated an HPSA for one of the other types of professional services, such as vision care, any group practice located solely in the HPSA and providing services that are of the type related to the HPSA designation, such as ophthalmology services, will be exempt from the ''substantially all'' calculation. On the other hand, if an area is an HPSA for vision care professionals (and for no other type of professional services), group practices providing services

unrelated to vision care in that area will not be exempt from the ''substantially all'' calculation. There appears to be no justification to exempt such group practices from the ''substantially all'' calculation in these cases, since there may not be a shortage for such services.

Our second change to the ''substantially all'' criteria involves group practices located outside an HPSA, but whose members provide services in an HPSA. These outside group practices must continue to meet the ''substantially all'' test, even if their members provide services in an HPSA. However, we are excluding from the ''substantially all'' calculation for those groups outside an HPSA any time spent by group members providing the appropriate services in a particular type of HPSA (as described above), whether that time in the HPSA is spent in a group practice, clinic, or an office setting. We have amended § 411.351 (''Definitions'') to reflect these concepts. We have also included a definition of ''HPSA'' in that section.

8. Ambulatory Surgical Center Exception

Comment: One commenter indicated that the Secretary should provide an exception for laboratory services performed in an ambulatory surgical center (ASC). Specifically, the exception should be provided if—

- Any ownership interest of the physician is in the ASC as a whole; and
- Any compensation relationship of the physician with the ASC does not relate to the provision of clinical laboratory services.

Response: We do not entirely agree with this comment. ASC facility services are services that are furnished by an ASC in connection with a covered surgical procedure and that would otherwise be covered if furnished on an inpatient or outpatient basis in a hospital in connection with that procedure. Medicare regulations at § 416.61 describe the scope of facility services. Generally, clinical laboratory services are not considered to be facility services. That is because, under § 416.61(b), ASC facility services do not include items and services for which payment may be made under other provisions in 42 CFR part 405, such as physicians' services, laboratory services, and x-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure). As a result, there are a limited number of diagnostic laboratory tests that are considered ASC facility services and which are included in the ASC rate. We agree with the commenter that referrals for laboratory tests that are performed in an ASC and included in the ASC rate should be excepted because there is no incentive to overutilize these services.

On the other hand, some ASC's have onsite laboratories that perform and bill for other laboratory testing furnished to ASC patients. Before enactment of CLIA, these laboratories were certified as ''independent laboratories'' and billed Medicare directly for their services. These laboratory facilities are now required to be certified under CLIA and continue to bill the Medicare program for the laboratory testing performed on the ASC premises, since general laboratory testing is not considered to be part of the ASC facility rate. We believe that, if the onsite laboratory facility is owned or operated by the ASC, referrals to the laboratory for general laboratory testing by a physician who has a financial relationship with the ASC should be prohibited, unless another statutory exception applies.

9. Home Care and Hospice Exception

Comment: One commenter indicated that home health agencies (HHAs) and hospices receive referrals from physicians to provide an array of services in the home. Currently, HHAs and hospices do not bill the Medicare program separately for laboratory services; instead, they bill for a home visit or the per diem hospice charge. The commenter made the following two recommendations:

- The regulations should clearly state that the prohibition does not apply to referrals to entities that do not bill Medicare separately for laboratory testing.
- Another exception should be developed to specify that the Medicare rules governing physician interest in HHAs would also apply to those entities in relation to laboratory services ordered by physicians. Thus, a physician's interest in a clinical laboratory would be permitted if the interest is less than 5 percent.

Response: As discussed earlier, OBRA '93 expanded the list of services subject to the prohibition to include 10 additional services. Because the list of services subject to the prohibition includes home health services, we do not believe an exception for laboratory services provided by home health agencies is warranted.

We agree with the commenter that referrals for laboratory tests that are performed by a hospice and are included in the per diem hospice charge should be excepted because a per diem amount does not reflect the number of tests performed. As a result, we are providing an exception in § 411.355 for laboratory services that are provided by a hospice and billed as part of the per diem rate.

We disagree with the commenter's second recommendation. Section 1877 prohibits referrals to an entity by a physician who has a financial relationship with that entity. A financial relationship consists of an ownership or investment interest in the entity, regardless of the extent or degree of that ownership interest. Therefore, if a physician owns 5 percent or 95 percent of an entity, he or she is prohibited from making referrals to that entity, unless some exception applies. We will not grant an extra exception for ownership interests that are less than a particular percentage or that involve HHAs. That is because we do not have any evidence upon which to base a percentage or to ensure that the exception would be free from any risk of program or patient abuse.

10. Rural Laboratory Compensation Arrangements

Section 1877(d)(2) provides that ownership or investment by a physician in a rural provider of clinical laboratory services will not prohibit referrals by the physician to that rural provider.

Comment: One commenter stated that the statutory exception for rural laboratories is of little value since it provides only an exception to the ownership or investment interest test and still leaves the rural laboratory subject to the compensation arrangement test. Thus, the commenter recommended that the final rule contain an exception for compensation arrangements between a rural laboratory and a referring physician.

Response: Because of the OBRA '93 amendments to section 1877, we do not believe the exception recommended by the commenter is necessary. Section 1877 now contains exceptions that we believe will cover many compensation arrangements between physicians and laboratories. In addition to the section 1877(d)(2) ownership exception for rural laboratories, section 1877(e)(2) provides an exception if a laboratory compensates a physician as the result of a bona fide employment relationship, and section 1877(e)(3) provides an exception for remuneration from an entity to a physician under a personal services arrangement between the physician and entity. Finally, there are other additional exceptions relating to various other compensation relationships that a physician might have with a laboratory. For example, under section 1877(e)(8), a physician can purchase clinical laboratory services from a laboratory, or other items and services from a laboratory at fair market

value, without triggering the prohibition. These exceptions apply to relationships with all laboratory entities, including those located in rural areas, provided the conditions set forth in the statute and this final regulation are met.

11. Case-by-Case Exemptions

Comment: One commenter indicated that we should institute a process by which a laboratory may request an exemption from the law on an individual basis, based upon a determination by the Secretary that enforcement of the prohibition against the laboratory would not be in the public interest. The commenter suggested that narrow guidelines should be established for the types of laboratories that would be eligible to apply for this exemption. Thus, in the commenter's view, the administrative burden would not be prohibitive. The commenter proposed that, in order to be eligible for review, that any one of the following criteria be met:

- The laboratory is wholly owned by one referring physician or one group practice. This requirement would exclude the physician joint venture type laboratories, which this commenter believed are the entities intended to be regulated by the law.
- Referrals to a laboratory by physicians who have financial relationships with the laboratory do not exceed a specified percentage of the total laboratory volume. The commenter suggested that the referrals be limited to 40 percent of the laboratory's total volume, consistent with the Medicare anti-kickback investment safe harbor volume criterion. (See 42 CFR part 1001.)
- A laboratory located in a town or similar-type population center with a population of 10,000 or under should be eligible for exemption review if it is the sole outpatient provider of certain laboratory services within that locality. This would recognize that localities that are within an MSA may, in fact, be small towns lacking adequate outpatient laboratory services.

Response: We do not agree that we should implement such a process. Section 1877(b)(4) specifies that, in addition to the exceptions described in the statute, the section 1877(a)(1) prohibition will not apply with respect to any other financial relationship which the Secretary determines, *and specifies* in *regulations*, does not pose a risk of program or patient abuse (emphasis added). The statute speaks in terms of excepting particular financial relationships according to rules that would apply to any person or entity that has such a relationship. It does not authorize ''case by case'' exceptions.

In addition, we do not believe that the guidelines suggested by the commenter to single out those who are eligible for case-by-case review would provide a guarantee against patient or program abuse. It is not clear to us why the review should only be available when a laboratory is wholly owned by one referring physician or one group practice. The commenter's second guideline would allow a laboratory entity to derive 40 percent of its business from referrals by physicians with whom the entity has a financial relationship. We do not believe that this standard would, in any way, satisfy the requirement under section 1877(b)(4) that exceptions beyond those specified in the law pose no risk of program or patient abuse. We simply do not see how a standard excusing any percentage of referrals would guarantee no risk of abuse.

Finally, we understand that it might be possible that a laboratory located within an MSA could have its existence threatened if it cannot accept referrals from physicians with whom it has financial relationships. The commenter did not, however, identify any specific localities, so we cannot tell how likely it is for this to occur. In any case, any such exception must be shown to comply with the ''no abuse'' criterion, and the commenter has provided us with no evidence that such an exception would be free of abuse. For these reasons, we are not adopting this suggestion.

12. Physician Ownership of Public Companies

Section 411.357(a)(2) of the proposed regulation provided an exception for a physician's or family member's ownership in a publicly owned corporation, provided that the ownership interest met certain requirements. Among these were the requirement that the corporation have, at the end of its most recent fiscal year, total assets exceeding $100 million. This requirement reflected section 1877(c)(2) of the statute. OBRA '93 amended the statute to require, instead, stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years. SSA '94 made this amendment effective retroactive to January 1, 1992. However, it also provided that, until January 1, 1995, a corporation could still meet the requirement in the exception if it qualified under the pre-OBRA '93 standard.

Comment: One commenter suggested that we create an exception allowing physicians to own shares in clinical laboratories that satisfy the first test of the statutory public-company exception (having publicly-traded securities on the specified national securities exchanges) whether or not the company has $100 million in assets (as required in proposed § 411.357(a)(2)), under certain conditions.

The conditions suggested were that: (1) The total physician ownership of each class of securities of the entity is less than 20 percent, and (2) no one physician's ownership of any class of securities of the entity represents more than 5 percent of the class. The commenter believed that such ownership would not pose a risk of abuse under Medicare. For example, the stock of Laboratory Corporation A, which has assets of $50 million, is owned by the following individuals. Laboratory Corporation A has only one class of stock.

Individual	Percentage
Dr. Abe	5
Mr. Brown	17
Dr. Car	5
Mr. Dorr	17
Dr. Else	5
Mr. Frank	17
Mr. Green	12
Mr. Hann	12
	100

In this example, no one physician owns more than 5 percent of the stock of Laboratory Corporation A and the total physician ownership is 15 percent. The commenter stated that these facts should allow the owner-physicians to refer to Laboratory Corporation A because, in the commenter's view, since the majority of stockholders are nonphysicians, the physicians have no incentive to overutilize laboratory testing to increase the value of their investments. The commenter concluded, therefore, that there would not be the risk of patient or program abuse.

Another commenter suggested that we create an exception for public companies similar to that of the safe harbor for investment interest under the anti-kickback statute. Generally, the commenter suggested that the exception should follow all of the requirements found in 42 CFR 1001.952(a), ''Investment interests safe harbor.''

Response: The second comment is related to the first, in that one of the requirements found in § 1001.952(a)

also establishes a percentage limit on the amount of the investment. That is, § 1001.952(a)(2)(i) specifies that, in order to qualify for the safe harbor exception, ''[n]o more than 40 percent of the value of the investment interests of each class of investments may be held * * * by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity.''

While each commenter has made a good suggestion, we do not have any data supporting the first commenter's assumption that a limit of 5 percent ownership of a class of securities by individual physicians and a limit of up to 20 percent ownership of a class of securities by all physicians poses no risk of abuse. We believe that the Congress was very deliberate in establishing the requirements for the exception based on ownership or investment in publicly traded securities that is found in section 1877(c). Further, as pointed out in an earlier response, in order to establish additional exceptions, we must determine that the financial relationship does not pose a risk of program or patient abuse. To adopt the suggested approaches, we would, for example, be required to justify why a total of 20 percent physician ownership in a company would be abusive while a total of less than 20 percent physician ownership in a company would not be abusive. We do not have data to justify such a distinction.

13. Compensation Exception

Comment: One commenter proposed that an additional exception to the prohibition on referrals be added to address certain compensation arrangements between clinical laboratories and physicians. This commenter stated that, under a typical contractual arrangement between a clinical laboratory and a physician, the physician pays a reasonable fee to a laboratory to provide a service in an area in which the physician or his or her office personnel lack expertise. Some examples would be assisting the physician to establish a billing service, providing management services, and hosting educational seminars. The commenter suggested that this exception could contain the following elements:

- The agreement must be in writing and be signed by all of the parties.
- The agreement must be for identifiable services, which must be clearly set forth in the agreement.
- Compensation must be consistent with fair market value for these services.
- The compensation must be considered commercially reasonable even if no referrals were made.
- The amount of compensation for the services must not vary based on the volume or value of any referrals of business by the physician.
- The services must be offered by the clinical laboratory to all physicians.
- There must be no requirement on the part of the physician to refer patients.

As described, this situation involves a payment by the physician to the laboratory under the terms of a contract.

Response: We agree that physicians incur a legitimate cost when they must provide certain services, such as continuing medical education for themselves and their staff members. In addition, the physicians should be able to determine where they can best get these services. The commenter has asked that we add a new exception to the prohibition on referrals to address certain compensation arrangements in which a physician pays a reasonable fee to a laboratory to provide a service in an area in which the physician or his or her office personnel lack expertise. We believe that an additional exception under the authority of section 1877(b)(4) is not necessary. Section 1877(e)(8), as added by OBRA '93, provides an exception for payments made by a physician to any entity as compensation for items and services (other than clinical laboratory services) if the items or services are priced at fair market value. This provision is effective retroactively to January 1, 1992, and is included at § 411.357(i) of this rule.

Comment: A few commenters noted that a laboratory encounters a problem, for the following reasons, if it has an employee who is related to a physician who refers work to the laboratory. The referral prohibition is triggered not only by physicians who themselves have financial relationships with a laboratory entity but also by a physician's immediate relatives who have financial relationships. As a result, the laboratory's payment to an employee can constitute a compensation arrangement and, under the proposed rule, the laboratory would not be permitted to accept referrals from that physician. The commenters suggested that, as long as the employer has a bona fide employment relationship with the employee, there is no reason to question these employment arrangements. The commenters suggested that, with an added exception, the laboratory would be able to avoid the burdensome process of polling its employees to determine if they have a relative who is a referring physician.

Response: Section 1877(e)(2), as amended by OBRA '93, establishes a new exception for bona fide employment situations between an entity and a physician or an immediate family member of a physician. The conditions for the exception are as follows:

- The employment arrangement is for identifiable services.
- The amount of the remuneration under the employment—
  + Is consistent with the fair market value of the services, and
  + Is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.
- The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.
  + The employment meets such other requirements as the Secretary may impose by regulations as needed to protect against program or patient abuse.

Finally, the employees may be paid a productivity bonus based on services they personally performed.

V. Analysis of and Responses to Public Comments on the Interim Final Rule With Comment Period—Reporting Requirements for Financial Relationships Between Physicians and Health Care Entities That Furnish Selected Items and Services

Section 152(a) of SSA '94 amended the reporting requirements in section 1877(f) of the Act. As amended, section 1877(f) specifically applies to not only physicians with an ownership or investment interest in an entity, but to physicians who have a compensation arrangement with an entity as well. SSA '94 also eliminated the Secretary's authority to waive the reporting requirements for certain States or services, although the Secretary continues to have the right to determine that an entity is not subject to the reporting requirements because it provides services covered under Medicare very infrequently. In addition, the reporting requirements continue to not apply to designated health services furnished outside of the United States.

The SSA '94 amendments apply to referrals made on or after January 1, 1995. However, section 1877(f) does not apply to referrals at all, but instead requires providers of Medicare covered items and services to report certain information about their financial relationships with physicians at such times as the Secretary specifies. As such, section 152(d), the effective date provision for the SSA '94 amendments,

is silent on when the amendments would apply to a provision that has no nexus with referrals. If section 152 is silent on this issue, we believe that the effective date is the date of enactment of the amendments, which is October 31, 1994. We have incorporated the amendments to section 1877(f) into § 411.361, to apply to any future reporting that we require.

Below we summarize and respond to comments we received in response to the interim final rule with comment period that was published in the **Federal Register** on December 3, 1991 (56 FR 61374). We received timely comments from five organizations.

Near the end of calendar year 1991, we developed a questionnaire titled ''Survey of Financial Relationships Between Physicians and Selected Health Care Entities'' (form HCFA–95) and forwarded it to selected hospitals, ESRD facilities, suppliers of ambulance services, entities furnishing diagnostic imaging (including magnetic resonance imaging, computerized axial tomography scans, ultrasound, and other diagnostic imaging services), parenteral and enteral suppliers, and entities furnishing physical therapy services. (This survey was also known as the ''Ten State Survey.'') This process was a collection of information concerning the financial interest arrangements of any entity that furnishes selected items and services for which payment may be made under Medicare. The survey was to be completed by all entities furnishing the above listed covered items and services to Medicare beneficiaries. The scope of the survey was limited to entities in the following 10 States: Connecticut, Pennsylvania, West Virginia, South Carolina, Florida, Michigan, Ohio, Texas, Arkansas, and California.

Surveys were sent to those entities that submitted claims to the Medicare intermediary or carrier for more than 20 items or services in any of the selected categories during calendar year 1990. Originally, an entity was required to return the survey not more than 30 days after the entity received it. Shortly after December 3, 1991, the date contractors were instructed to send the surveys via overnight, certified mail, the response time was extended from 30 days from the date of receipt to 60 days from the date of receipt.

Two commenters applauded our citing the need for the survey because of the potential for abusive behavior in situations where the referring physician has an ownership interest in the facility to which he or she refers patients. A discussion of other comments and our responses to them follow.

Comment: One commenter suggested that requiring the completed survey to be submitted before or at the same time that the comments on the interim final rule were due made the opportunity to comment meaningless.

Response: We agree that the timing of the deadlines for the completed survey and the comments on the interim final rule could be regarded as having had the effect of reducing a commenter's ability to have an impact on that particular survey. As we pointed out in the preamble to the interim final rule, however, section 4207(k) of OBRA '90 authorized the Secretary to issue interim final regulations for the amendments to the Medicare statute. In the preamble, we explained the pressing need for the interim final rule in order for us to fulfill several legislative requirements within their prescribed deadlines. These included carrying out the survey requirements of section 1877(f), as amended by OBRA '90, obtaining adequate information from health care entities in time to apply the payment provisions in section 1877, as amended by OBRA '90, and preparing the statistical profile required by OBRA '89, as amended by OBRA '90.

The purpose of the interim final rule was primarily to notify the public of the decisions the Secretary had made on the few items of discretion left to the Secretary under OBRA '90, such as the selection of the States in which the survey would be administered (the legislation prescribed a minimum of 10 States). In addition, we do not regard the opportunity that was provided to comment on the interim final rule as meaningless. Section 1877 allows the Secretary to collect the survey information in such form, manner, and at such times as she specifies, as long as it is first collected no later than October 1, 1991. The Secretary will take the comments into account if she decides to survey the entities again.

Comment: One commenter suggested that we extend the time for responding to the survey by 60 days and announce the extension publicly.

Response: As noted, we did provide for an automatic extension of 30 days, allowing a total of 60 days for response. We provided 19 representative specialty societies, for example, the American Medical Association, the American Hospital Association, and the American College of Radiology, with this information to alert their members. In addition, we alerted Medicare contractors who, in turn, alerted providers via updates in their routinely distributed bulletins and newsletters.

Comment: One medical specialty association had received several complaints from its members concerning the question of who must report the ownership interest and what information must be reported. The association stated that the definition of ''entity'' (physicians, suppliers, or providers) in the instructions was too broad.

Response: The statute at section 1877(f) required, prior to SSA '94, that ''*[e]ach* entity providing covered items or services for which payment may be made under [Medicare] shall provide the Secretary with the information concerning the entity's ownership arrangements, * * *.'' (Emphasis added.) The statute does not define an ''entity.'' Thus, we could include within this concept any individuals or groups that provided Medicare covered items or services. We surveyed every entity, regardless of type, that provided more than 20 services in 1990 from the minimum set of services (hospital services, ambulance services, etc.) covered by the statutory requirement for this study. The use of the terms ''physicians, suppliers, or providers'' in our survey instructions was meant to cover all types of entities that had provided more than 20 services during 1990 of the types listed in the legislation.

Comment: One commenter wrote that there was no question on the survey that distinguished between those physicians who have an ownership interest in a facility and those who do not, like hospital-based radiologists. The commenter recommended that information relative to hospital-based practices be extracted and excluded from the study as it could produce a flawed database.

Response: We are not certain of the point this commenter wanted to make. Our survey form clearly distinguished between physicians with an ownership interest in an entity and physicians compensated by an entity, such as hospital-based radiologists. After receiving these survey forms, we matched data from the forms to Medicare claims data to determine referral patterns to entities that had submitted these survey forms. Since we also had information for each entity billing the program relating to whether the patient was referred to the entity by a physician with an ownership interest or by a physician compensated by the entity, the study was able to determine the referral patterns to that entity in a totally objective manner.

Comment: Two commenters wrote that the regulations would result in unreasonably burdensome reporting obligations for certain health care entities. The commenters believed that

the collection of useless information will thwart, rather than support, legitimate monitoring efforts. Examples of information that the commenters believed was unnecessary was identifying *all* physicians in a teaching hospital, considering the size of the facility, the number of salaried staff and faculty, and the time and effort required to collect, organize, check, and report the required data.

Response: The scope of the data collection activity was expansive in order to ensure that the Congress had sufficient information on utilization rates by physician owned and non-owned entities to consider in its legislative activities. While this may have appeared to be more data than could be effectively used, we believed a more narrow data collection effort would have resulted in the Congress having insufficient facts when considering legislative alternatives. Surveyed entities were expected to make good faith efforts to complete the surveys accurately, completely, and timely. In addition, we granted extensions to the 60-day response period on a case-by-case basis.

Comment: One commenter opposed the requirement that hospitals report compensation/remuneration arrangements, because the requirement exceeds the scope of section 1877(f) of the Act.

Response: Prior to SSA '94, section 1877(f) did not specifically provide us with the authority to require that hospitals report compensation/remuneration arrangements. Section 1877(f) required that entities report only the ownership or investment interests of physicians. As we pointed out in the preamble to the interim final rule, however, we believed that other parts of section 1877, the payment provisions of the Medicare statute, and section 6204(f) of OBRA '89, as amended by OBRA '90, implicitly required us to collect this information.

As we pointed out at 56 FR 61376, we need the information on compensation/remuneration arrangements in order to enforce the general prohibition, in section 1877, against physicians referring to laboratories with which they have a financial relationship, including a relationship based on a compensation arrangement. Without the reporting requirement, we would not have sufficient information to make payment determinations. Also, we would not have had the data we needed to prepare the statistical profile required by section 6204(f) of OBRA '89, as amended by section 4207(e)(4) of OBRA '90. This provision required us to produce a profile that covered all of a physician's direct or indirect financial interests. As we explained earlier, beginning October 31, 1994, § 152(a) of SSA '94 amended § 1877(f) to explicitly require that a reporting entity provide information concerning the entity's ownership, investment, and compensation arrangements.

Comment: One commenter suggested that the imposition of civil monetary penalties on reporting entities that fail to report compensation/remuneration arrangements in a timely manner exceeds our statutory authority.

Response: Section 1877(g)(5) provides a civil money penalty when a person fails to meet the reporting requirements of section 1877(f). Section 1877(f), prior to OBRA '93, concerned information related to ownership interests only. However, as the result of the changes made in § 1877(f) by § 152(a) of SSA '94, entities are now required to provide information about ownership, investment, and compensation arrangements. As a result, we now have the authority to impose a civil money penalty when an entity fails to provide any of these kinds of information.

Comment: One commenter from California suggested that reporting employee information would place a hospital in jeopardy of violating certain State laws and State regulations.

Response: As we stated in an earlier comment, we have interpreted section 1877, the payment provisions of the Medicare statute, and section 6204(f) of OBRA '89 as requiring that reporting entities provide us with information about all of their financial relationships with a physician or a physician's family member. The statute at § 1877(f) now requires this information for all ownership, investment, and compensation arrangements. If this explicit Federal requirement conflicts with State law or State regulations, the Federal law and Federal regulations prevail.

VI. Provisions of This Final Rule

We have extensively rearranged the regulations from what we proposed and have added numerous OBRA '93 provisions as amended by SSA '94. Because of these many changes, we are including, in section VI.C., a list identifying whether the requirements in this final rule derive from OBRA '93, SSA '94, the proposed rule, or comments on the proposed rule. In addition, we identify below the changes from the December 1991 interim final rule and the March 1992 proposed rule.

A. Proposed Rule—Physician Ownership of, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services

Based on our analysis of the comments, we are adopting the provisions as set forth in the March 1992 proposed rule, with the following changes. The reason for a change either has been discussed in section IV of this preamble, the change is a result of the provisions of OBRA '93 or SSA '94, or the change merely conforms the regulations to the statute.

- In § 411.1 (''Basis and scope''), we added that section 1877 of the Act sets forth limitations on referrals and payment for clinical laboratory services furnished by entities with which an immediate family member of the referring physician has a financial relationship. This change was made to conform the regulation to the statute.
- As a result of the comments we received, we revised the definition of ''compensation arrangement'' at § 411.351 (''Definitions'') to clarify that it applies to direct and indirect arrangements.
- We revised the definition of ''group practice'' at § 411.351 as follows:
  + Revised the ''substantially all'' threshold to 75 percent of the total patient care services of group practice members, measured as ''patient care time.''
  + Expanded and moved, to a new § 411.360, the requirements related to the group practice attestation statement.
  + Provided an exception to the ''substantially all'' requirement for those services furnished through a group practice located solely in certain areas designated as HPSAs under § 411.351. Also specified in this section that when members of a group practice that is located outside an HPSA spend time providing services in certain HPSAs, that time is not used to calculate the outside group's ''substantially all'' standard.
- We removed the definitions of ''interested investor'' and ''investor'' from § 411.351.
- We revised the definition of ''remuneration'' at § 411.351 to provide that forgiveness of debts, certain payments, and the furnishing of certain items, devices, and supplies are not considered remuneration if they meet specified conditions.
- We added a definition of ''clinical laboratory services,'' ''direct supervision,'' ''hospital,'' ''HPSA,'' ''laboratory,'' ''members of the group,'' ''patient care services,'' ''physician incentive plan,'' ''plan of care,'' and ''transaction'' to § 411.351.

• We revised § 411.355 (''General exceptions to referral prohibitions related to both ownership/investment and compensation'') to do the following:

+ For purposes of the in-office ancillary services exception in § 411.355(b), require that individuals furnishing services be ''directly'' supervised by the referring physician or by another physician in the same group practice. (The proposed rule had required that services be provided by an employee who was ''personally'' supervised by these physicians.)

+ Include among the locations where the service may be furnished a building that is used by the group practice for the provision of some or all of the group's clinical laboratory services. (The proposed rule had required that the building be used by the group practice for centrally furnishing the group's clinical laboratory services.)

• We added the following services to the general exceptions listed under § 411.355 (''General exceptions to referral prohibitions related to both ownership/investment and compensation''):

+ Services furnished by a qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act) to individuals enrolled in the organization (new § 411.355(c)(4)).

+ Services furnished in an ASC or ESRD facility or by a hospice and included in the ASC rate, ESRD composite rate, or per diem hospice charge, respectively (new § 411.355(d)).

• We revised proposed § 411.357, now designated as § 411.356, (''Exceptions to referral prohibitions related to ownership or investment interests'') to—

+ Revise the requirements relating to publicly-traded securities, as specified in section 1877(c) of the Act (as amended by OBRA '93 and SSA '94), to include securities which ''may be purchased'' on terms generally available to the public, which can be those traded on additional stock markets, and which can be in corporations that had the following:

—Until January 1, 1995, total assets at the end of the corporation's most recent fiscal year exceeding $100 million, or

—Stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year, or on average during the previous 3 fiscal years

+ No longer specify, with regard to the corporation's assets, that these assets must have been obtained in the normal course of business and not for the primary purpose of qualifying for the exception;

+ Expand the exception to include mutual funds that constitute ownership in shares in certain regulated investment companies, if the companies had, at the end of their most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75 million.

+ Until January 1, 1995, retained the exception for a hospital located outside of Puerto Rico based on the condition that the referring physician's ownership or investment interest does not relate to the furnishing of clinical laboratory services.

+ Revise the requirements relating to rural providers, as specified in the proposed rule, to delete paragraph (ii), which added the requirement that the majority of tests referred to the rural laboratory are referred by physicians who have office practices located in a rural area.

+ Revise the requirements relating to rural providers, as specified in the proposed rule, to include the requirement that substantially all of the tests furnished by the entity are furnished to individuals residing in a rural area.

• We revised proposed § 411.359, now designated as § 411.357, (''Exceptions to referral prohibitions related to compensation arrangements'') to do the following:.

+ Revise (a)(1) to reflect new requirements specified by OBRA '93 for the rental of space.

+ Remove proposed paragraph (a)(2), which contained requirements related to a physician who has an ownership or investment interest in a laboratory and who also rents or leases space to the laboratory.

+ Add an exception for rental of equipment under certain conditions (new § 411.357(b)).

+ Add an exception for certain group practice arrangements with a hospital (new § 411.357(h).

+ Add an exception for payments by a physician to a laboratory or other entity in exchange for certain items and services (new § 411.357(i)).

+ Replace proposed § 411.359(b) (''Employment and service arrangements with hospitals'') and proposed § 411.359(f) (''Salaried physicians in a group practice'') with a new § 411.357(c) (''Bona fide employment relationships''). New § 411.357(c) is based on the exception at section 1877(e)(2) of the Act.

+ Replace proposed § 411.359(e) (''Service arrangements with non-hospital entities'') with a new § 411.357(d) (''Personal service arrangements''). New § 411.357(d) is based on the exception at section 1877(e)(3) of the Act.

• We added a new § 411.360 that requires that a group practice submit annually a statement attesting that it met the ''substantially all'' test set forth, under the definition of ''group practice,'' in § 411.351 of this rule. This section also specifies how a newly-formed group practice meets the ''substantially all'' criterion.

In addition to the above changes, we have made technical changes. For example, in proposed § 411.355(c)(1), we cross-referenced part 417, subpart C. Subpart C has been redesignated by a new rule. The applicable provisions being cross-referenced are now under subparts J through M. We have also made editorial changes that do not affect the substance of the provisions.

B. Interim Final Rule With Comment Period—Reporting Requirements for Financial Relationships Between Physicians and Health Care Entities That Furnish Selected Items and Services.

The interim final rule with comment published on December 3, 1991, is revised to incorporate the amendments to section 1877(f) made by SSA '94, to apply to any future reporting that we require. However, providers will not be held to the reporting requirements under section 1877(f) until we develop and issue the proper form and accompanying instructions booklet. Until that time, we will use audits and investigations as the primary tools to evaluate compliance with these provisions.

C. Source of Final Regulations.

Final regulations	Source
§ 411.1 Basis and scope	Proposed § 411.1.
§ 411.350 Scope of subpart	Proposed § 411.350, SSA '94.
§ 411.351 Definitions	§ 411.351.
Clinical laboratory services	Comments.
Compensation arrangement	Proposed § 411.352 and comments.
Direct supervision	Comments and OBRA '93.

Final regulations	Source
Employee	Proposed § 411.351.
Entity	Proposed § 411.351.
Fair market value	Proposed § 411.351.
Financial relationship	Proposed § 411.351.
Group practice	Proposed § 411.351, OBRA '93, and Comments.
HPSA	Comments.
Immediate family member	Proposed § 411.351.
Laboratory	Comments.
Members of a group	Comments.
Patient care services	Comments.
Physician incentive plan	OBRA '93.
Plan of care	Comments.
Referral	Proposed § 411.351 and Comments.
Referring physician	Proposed § 411.351.
Remuneration	Proposed § 411.351 and OBRA '93.
Transaction	Comments.
§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.	Proposed § 411.353.
(a) Prohibition on referrals	Proposed § 411.353(a).
(b) Limitations on billing	Proposed § 411.353(b).
(c) Denial of Payment	Proposed § 411.353(c).
(d) Refunds	Proposed § 411.353(d).
§ 411.355 General exceptions to referral prohibitions related to ownership and compensation	Proposed § 411.355.
(a) Physicians' services	Proposed § 411.355(a).
(b) In-office ancillary services	Proposed § 411.355(b) and services OBRA '93.
(c) Services furnished to prepaid health plan enrollees	Proposed § 411.355(c).
(c)(1) HMO or CMP under section 1876	Proposed § 411.355(c)(1).
(c)(2) Prepaid plan under section 1833(a)(1)(A)	Proposed § 411.355(c)(2).
(c)(3) An organization receiving payments through a demonstration project	Proposed § 411.355(c)(3).
(c)(4) A qualified HMO within the meaning of section 1310(d) of the Public Health Service Act.	OBRA '93.
(d) Services furnished in an ASC or ESRD facility	Comments.
§ 411.356 Exceptions to referral prohibitions related to ownership or investment interests	Proposed § 411.357.
(a) Publicly-traded securities	Proposed § 411.357(a) and OBRA '93.
(b) Mutual funds	OBRA '93.
(c) Specific providers	Proposed § 411.357(b).
(c)(1) Rural laboratories	Proposed § 411.357(b)(1) and Comments.
(c)(2) Hospitals in Puerto Rico	Proposed § 411.357(b)(2).
(c)(3) Hospitals outside of Puerto Rico	Proposed § 411.357(b)(3), OBRA '93, SSA '94.
§ 411.357 Exceptions to referral prohibitions related to compensation arrangements	Proposed § 411.359.
(a) Rental of office space	OBRA '93.
(b) Rental of equipment	OBRA '93.
(c) Bona fide employment	OBRA '93.
(d) Personal service arrangements	
(d)(1) General	OBRA '93.
(d)(2) Physician incentive plan exception	OBRA '93.
(e) Physician recruitment	Proposed § 411.359(c).
(f) Isolated transactions	Proposed § 411.359(d), Comments, OBRA '93.
(g) Arrangements with hospitals	OBRA '93.
(h) Group practice arrangements with a hospital	OBRA '93.
(i) Payments by a physician	OBRA '93.
§ 411.360 Group practice attestation	Comments.
§ 411.361 Reporting requirements	Existing § 411.361 and SSA '94.

VII. Collection of Information Requirements

Regulations at § 411.360 contain information collection or recordkeeping requirements or both that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). The information collection requirements concern those group practices attempting to meet the definition found in section 1877(h)(4) and require them to attest that, in the aggregate, at least 75 percent of the total patient care services furnished by all physician members are furnished through the group and are billed under a billing number assigned to the group. Public reporting burden for this collection of information is estimated to be 1 hour per response. A document will be published in the **Federal Register** after approval is obtained. Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the OMB official whose name appears in the **ADDRESSES** section of this preamble.

VIII. Regulatory Impact Statement

A. Introduction

The provisions of this final rule with comment period implement section 6204 of OBRA '89 and section 4207(e) of OBRA '90, which concern a limitation on certain physician referrals. In addition, the rule contains revisions to our March 1992 proposal, based on comments submitted by the public. This final rule also incorporates the new expansions and exceptions created by OBRA '93, as amended by SSA '94, that are related to referrals for clinical laboratory services and have a

retroactive effective date of January 1, 1992. This final rule with comment, by prohibiting physician referrals for clinical laboratory services by physicians who have certain ownership, investment, or compensation arrangements with the entity furnishing the service, is meant to eliminate the ordering of unnecessary laboratory tests.

According to the OIG report cited in the March 1992 proposed rule (57 FR 8589), at least 25 percent of the nearly 4500 independent clinical laboratories, at the time of the report, were owned in whole or in part by referring physicians. The same OIG report revealed that Medicare patients of referring physicians who own or invest in these laboratories received 45 percent more clinical laboratory services than all Medicare patients. The OIG estimated in its report that the ''increased utilization of clinical laboratory services by patients of physician-owners cost the Medicare program $28 million nationally in 1987.'' (Financial Arrangements Between Physicians and Health Care Businesses, (May 1989))

We believe the majority of physicians and clinical laboratories do not currently make referrals that are prohibited by this rule. In addition, we believe that, in response to the statutory provisions, many physicians and laboratories took necessary steps, before January 1, 1992, to ensure that their investment and employment activities did not restrict their ability to make referrals. Therefore, any estimate of the aggregate economic impact of this rule will be purely speculative. We believe the statute itself will have a continuing deterrent effect on physicians' aberrant referral patterns and investment interests.

B. Regulatory Flexibility Act

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all hospitals, physicians, and clinical laboratories to be small entities.

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

We expect that a few entities may be affected to varying degrees by this final rule. Relative to the potential impact on these entities, the following discussion is provided.

1. Impact on Physicians and Physician Groups

Physicians reportedly find it inefficient and inconvenient to split their laboratory referral business among multiple laboratories; the physician who uses one laboratory for private-pay patients is likely to use that same laboratory for all of his or her patients. Therefore, it is conceivable that, absent this rule, a physician could seek an ownership or investment interest in a laboratory, or a compensation arrangement with a laboratory, in order for the physician to share in the profits of the laboratory to which he or she makes referrals. In these cases, the prohibition on referrals might apply, which will require the physician to either dispose of his or her interest in the laboratory or stop referring Medicare patients to that laboratory.

As discussed at length earlier in this preamble, some physicians who have independent practices maintain a physician office laboratory with other physicians in shared premises, with shared equipment, shared employees, a shared administrator who has the power to hire and terminate employees on behalf of the physicians, and shared overhead costs. For the most part, these shared office space arrangements are not eligible for the in-office ancillary exception found in section 1877(b)(2) and, therefore, the prohibition on referrals does apply. Thus, the physicians must each separately meet the in-office ancillary services requirements, form a group practice meeting the definition of section 1877(h)(4) of the Act, dispose of their interest in the shared laboratory facility, or stop referring Medicare patients to that laboratory facility.

Also as discussed earlier, in response to OBRA '93 changes, we have added exceptions to the prohibition on referrals that we believe recognize existing medical practice, are reasonable, and will not result in program abuse.

As a result of public comments we received in response to the proposed rule, we are revising the definition of ''group practice'' (§ 411.351) by lowering the ''substantially all'' threshold from 85 percent to 75 percent of the total patient care services of group practice members. This change will allow groups of physicians additional flexibility in hiring part-time and temporary physicians, without the group jeopardizing its standing as a group practice.

2. Impact on Laboratories

As mentioned earlier in this impact statement, the report from the OIG to the Congress indicated that at least 25 percent of the nearly 4500 independent clinical laboratories were owned in whole or in part by referring physicians. The same report found that Medicare ''patients of referring physicians who own or invest in these laboratories received 45 percent more clinical laboratory services than all Medicare patients * * *.'' Other studies found equivalent correlations involving physician self-referrals. However, we are unable to estimate with any degree of accuracy how existing physician laboratory owners will react to the provisions of the law and this rule or how the utilization of laboratory services will change. Nevertheless, given the extensive reach of section 1877 of the Act and these final regulations and the substantial penalties that are provided for violations of the prohibition on referrals, we believe that laboratories and physicians have been restructuring their relationships to ensure compliance with the statute and will continue to do so.

3. Impact on Hospitals

Sections 411.356 (b)(2) and (b)(3) include exceptions related to the prohibition on referrals for ownership or investment interests in certain hospitals. Sections 411.357 (c), (d), (e), (g), and (h) include exceptions related to the prohibition on referrals for compensation for services performed or supervised by physicians. Because we believe that a large number of the financial relationships between physicians and hospitals are covered by these exceptions, we do not believe hospitals will be significantly affected by this rule. In addition, hospitals in Puerto Rico and many hospitals in rural areas are excluded from this rule under § 411.356(c).

For the reasons stated above, we have determined, and the Secretary certifies, that this final rule with comment will not result in a significant economic impact on a substantial number of small entities or on the operations of a substantial number of small rural hospitals. We are, therefore, not preparing analyses for either the RFA or section 1102(b) of the Act.

In accordance with the provisions of E.O. 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

42 CFR part 411 is amended as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

1. The authority citation for part 411 is revised to read as follows:

Authority: Secs. 1102, 1834, 1842(l), 1861, 1862, 1871, 1877, and 1879 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395u(l), 1395x, 1395y, 1395hh, 1395nn, and 1395pp).

2. In § 411.1, paragraph (a) is revised to read as follows:

§ 411.1 Basis and scope.

(a) *Statutory basis.* Sections 1814(c), 1835(d), and 1862 of the Act exclude from Medicare payment certain specified services. The Act provides special rules for payment of services furnished by Federal providers or agencies (sections 1814(c) and 1835(d)), by hospitals and physicians outside the United States (sections 1814(f) and 1862(a)(4)), and by hospitals and SNFs of the Indian Health Service (section 1880). Section 1877 sets forth limitations on referrals and payment for clinical laboratory services furnished by entities with which the referring physician (or an immediate family member of the referring physician) has a financial relationship.

* * * *

3. Section 411.350 is revised to read as follows:

§ 411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for clinical laboratory services to an entity with which the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered items or services under Part A or Part B report information concerning their ownership, investment, or compensation arrangements in the form, manner, and at the times specified by HCFA.

4. New §§ 411.351, 411.353, 411.355 through 411.357, and 411.360 are added to read as follows:

§ 411.351 Definitions.

As used in this subpart, unless the context indicates otherwise:

Clinical laboratory services means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

Compensation arrangement means any arrangement involving any remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity.

Direct supervision means supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.

Employee means any individual who, under the usual common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed at 20 CFR 404.1007 and 26 CFR 31.3121(d)–1(c).)

Entity means a sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association.

Fair market value means the value in arm's-length transactions, consistent with the general market value. With respect to rentals or leases, *fair market value* means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee.

Financial relationship refers to a direct or indirect relationship between a physician (or a member of a physician's immediate family) and an entity in which the physician or family member has—

(1) An ownership or investment interest that exists in the entity through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing laboratory services; or

(2) A compensation arrangement with the entity.

Group practice means a group of two or more physicians, legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association, that meets the following conditions:

(1) Each physician who is a *member of the group,* as defined in this section, furnishes substantially the full range of patient care services that the physician routinely furnishes including medical care, consultation, diagnosis, and treatment through the joint use of shared office space, facilities, equipment, and personnel.

(2) Except as provided in paragraphs (2)(i) and (2)(ii) of this definition, substantially all of the patient care services of the physicians who are members of the group (that is, at least 75 percent of the total patient care services of the group practice members) are furnished through the group and billed in the name of the group and the amounts received are treated as receipts of the group. ''Patient care services'' are measured by the total patient care time each member spends on these services. For example, if a physician practices 40 hours a week and spends 30 hours on patient care services for a group practice, the physician has spent 75 percent of his or her time providing countable patient care services.

(i) The ''substantially all'' test does not apply to any group practice that is located solely in an HPSA, as defined in this section, and

(ii) For group practices located outside of an HPSA (as defined in this section) any time spent by group practice members providing services in an HPSA should not be used to calculate whether the group practice located outside the HPSA has met the ''substantially all'' test, regardless of whether the members' time in the HPSA

is spent in a group practice, clinic, or office setting.

(3) The practice expenses and income are distributed in accordance with methods previously determined.

In the case of faculty practice plans associated with a hospital, institution of higher education, or medical school that has an approved medical residency training program in which faculty practice plan physicians perform specialty and professional services, both within and outside the faculty practice, as well as perform other tasks such as research, this definition applies only to those services that are furnished within the faculty practice plan.

Hospital means any separate legally organized operating entity plus any subsidiary, related, or other entities that perform services for the hospital's patients and for which the hospital bills. A ''hospital'' does not include entities that perform services for hospital patients ''under arrangements'' with the hospital.

HPSA means, for purposes of this regulation, an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in 42 CFR part 5, appendix A, part I—Geographic Areas). In addition, with respect to dental, mental health, vision care, podiatric, and pharmacy services, an HPSA means an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for dental professionals, mental health professionals, vision care professionals, podiatric professionals, and pharmacy professionals, respectively.

Immediate family member or member of a physician's immediate family means husband or wife; natural or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

Laboratory means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Members of the group means physician partners and full-time and part-time physician contractors and employees during the time they furnish services to patients of the group practice that are furnished through the group and are billed in the name of the group.

Patient care services means any tasks performed by a group practice member that address the medical needs of specific patients, regardless of whether they involve direct patient encounters. They can include, for example, the services of physicians who do not directly treat patients, time spent by a physician consulting with other physicians, or time spent reviewing laboratory tests.

Physician incentive plan means any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.

Plan of care means the establishment by a physician of a course of diagnosis or treatment (or both) for a particular patient, including the ordering of items or services.

Referral—

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, any item or service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of laboratory services or the establishment of a plan of care by a physician that includes the provision of laboratory services.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services if—

(i) The request is part of a consultation initiated by another physician; and

(ii) The tests or services are furnished by or under the supervision of the pathologist.

Referring physician means a physician (or group practice) who makes a referral as defined in this section.

Remuneration means any payment, discount, forgiveness of debt, or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration:

(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(2) The furnishing of items, devices, or supplies that are used solely to collect, transport, process, or store specimens for the entity furnishing the items, devices, or supplies or are used solely to order or communicate the results of tests or procedures for the entity.

(3) A payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the plan and the physician;

(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.

Transaction means an instance or process of two or more persons doing business. An *isolated transaction* is one involving a single payment between two or more persons. A transaction that involves long-term or installment payments is not considered an isolated transaction.

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician who has a financial relationship with an entity, or who has an immediate family member who has a financial relationship with the entity, may not make a referral to that entity for the furnishing of clinical laboratory services for which payment otherwise may be made under Medicare.

(b) *Limitations on billing.* An entity that furnishes clinical laboratory services under a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare

program or to any individual, third party payer, or other entity for the clinical laboratory services performed under that referral.

(c) *Denial of payment.* No Medicare payment may be made for a clinical laboratory service that is furnished under a prohibited referral.

(d) *Refunds.* An entity that collects payment for a laboratory service that was performed under a prohibited referral must refund all collected amounts on a timely basis.

§ 411.355 General exceptions to referral prohibitions related to both ownership/investment and compensation.

The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:

(a) *Physicians' services,* as defined in § 410.20(a), that are furnished personally by (or under the personal supervision of) another physician in the same group practice as the referring physician.

(b) *In-office ancillary services.* Services that meet the following conditions:

(1) They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) Individuals who are directly supervised by the referring physician or, in the case of group practices, by another physician in the same group practice as the referring physician.

(2) They are furnished in one of the following locations:

(i) A building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of clinical laboratory services.

(ii) A building that is used by the group practice for the provision of some or all of the group's clinical laboratory services.

(3) They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member.

(iii) An entity that is wholly owned by the physician or the physician's group practice.

(c) *Services furnished to prepaid health plan enrollees by one of the following organizations:*

(1) An HMO or a CMP in accordance with a contract with HCFA under section 1876 of the Act and part 417, subparts J through M, of this chapter.

(2) A health care prepayment plan in accordance with an agreement with HCFA under section 1833(a)(1)(A) of the Act and part 417, subpart U, of this chapter.

(3) An organization that is receiving payments on a prepaid basis for the enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 note).

(4) A qualified health maintenance organization (within the meaning of section 1310(d) of the Public Health Service Act).

(d) *Services furnished in an ambulatory surgical center (ASC) or end stage renal disease (ESRD) facility, or by a hospice* if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.

§ 411.356 Exceptions to referral prohibitions related to ownership or investment interests.

For purposes of § 411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that may be purchased on terms generally available to the public and that meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; or

(ii) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers.

(2) In a corporation that had—

(i) Until January 1, 1995, total assets at the end of the corporation's most recent fiscal year exceeding $100 million; or

(ii) Stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities:

(1) A laboratory that is located in a rural area (that is, a laboratory that is not located in an urban area as defined in § 412.62(f)(1)(ii) of this chapter) and that meets the following criteria:

(i) The laboratory testing that is referred by a physician who has (or whose immediate family member has) an ownership or investment interest in the rural laboratory is either—

(A) Performed on the premises of the rural laboratory; or

(B) If not performed on the premises, the laboratory performing the testing bills the Medicare program directly for the testing.

(ii) Substantially all of the laboratory tests furnished by the entity are furnished to individuals who reside in a rural area. Substantially all means no less than 75 percent.

(2) A hospital that is located in Puerto Rico.

(3) A hospital that is located outside of Puerto Rico if one of the following conditions is met:

(i) The referring physician is authorized to perform services at the hospital, and the physician's ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital.

(ii) Until January 1, 1995, the referring physician's ownership or investment interest does not relate (directly or indirectly) to the furnishing of clinical laboratory services.

§ 411.357 Exceptions to referral prohibitions related to compensation arrangements.

For purposes of § 411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement that meets the following requirements:

(1) The agreement is set out in writing and is signed by the parties and specifies the premises covered by the lease.

(2) The term of the agreement is at least 1 year.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if

the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the lease are set in advance and are consistent with fair market value.

(5) The charges are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) A rental or lease agreement is set out in writing and signed by the parties and specifies the equipment covered by the lease.

(2) The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee.

(3) The lease provides for a term of rental or lease of at least 1 year.

(4) The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(5) The lease would be commercially reasonable even if no referrals were made between the parties.

(c) *Bona fide employment relationships.* Any amount paid by an employer to a physician (or immediate family member) who has a bona fide employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

(3) The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(d) *Personal service arrangements*—(1) *General.* Remuneration from an entity under an arrangement to a physician or immediate family member of the physician, including remuneration for specific physicians' services furnished to a nonprofit blood center, if the following conditions are met:

(i) The arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity.

(iii) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

(iv) The term of the arrangement is for at least 1 year.

(v) The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(vi) The services to be furnished under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(2) *Physician incentive plan exception.* In the case of a physician incentive plan between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled in the entity.

(ii) In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary under section 1876(i)(8)(A)(ii) of the Act, the plan complies with any requirements the Secretary has imposed under that section.

(iii) Upon request by the Secretary, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements of paragraph (d)(2) of this section.

(3) Until January 1, 1995, the provisions in paragraph (d) (1) and (2) of this section do not apply to any arrangements that meet the requirements of section 1877(e)(2) or section 1877(e)(3) of the Act as they read before they were amended by the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66).

(e) *Physician recruitment.* Remuneration provided by a hospital to recruit a physician that is intended to induce the physician to relocate to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

(1) The arrangement and its terms are in writing and signed by both parties.

(2) The arrangement is not conditioned on the physician's referral of patients to the hospital.

(3) The hospital does not determine (directly or indirectly) the amount or value of the remuneration to the physician based on the volume or value of any referrals the physician generates for the hospital.

(4) The physician is not precluded from establishing staff privileges at another hospital or referring business to another entity.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, if all of the conditions set forth in paragraphs (c)(2) and (c)(3) of this section are met with respect to an entity in the same manner as they apply to an employer. There can be no additional transactions between the parties for 6 months after the isolated transaction, except for transactions which are specifically excepted under the other provisions in §§ 411.355 through 411.357.

(g) *Arrangements with hospitals.* (1) Until January 1, 1995, any compensation arrangement between a hospital and a physician or a member of a physician's immediate family if the arrangement does not relate to the furnishing of clinical laboratory services; or

(2) Remuneration provided by a hospital to a physician if the remuneration does not relate to the furnishing of clinical laboratory services.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under

which clinical laboratory services are provided by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services provided to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before December 19, 1989, and has continued in effect without interruption since then.

(3) With respect to the clinical laboratory services covered under the arrangement, substantially all of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with an agreement that is set out in writing and that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(i) *Payments by a physician.* Payments made by a physician—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for other items or services that are furnished at a price that is consistent with fair market value.

§ 411.360 Group practice attestation.

(a) Except as provided in paragraph (b) of this section, a group practice (as defined in section 1877(h)(4) of the Act and § 411.351) must submit a written statement to its carrier annually to attest that, during the most recent 12-month period (calendar year, fiscal year, or immediately preceding 12-month period) 75 percent of the total patient care services of group practice members was furnished through the group, was billed under a billing number assigned to the group, and the amounts so received were treated as receipts of the group.

(b) A newly-formed group practice (one in which physicians have recently begun to practice together) or any group practice that has been unable in the past to meet the requirements of section 1877(h)(4) of the Act must—

(1) Submit a written statement to attest that, during the next 12-month period (calendar year, fiscal year, or next 12 months), it expects to meet the 75-percent standard and will take measures to ensure the standard is met; and

(2) At the end of the 12-month period, submit a written statement to attest that it met the 75-percent standard during that period, billed for those services under a billing number assigned to the group, and treated amounts received for those services as receipts of the group. If the group did not meet the standard, any Medicare payments made for clinical laboratory services furnished by the group during the 12-month period that were conditioned upon the standard being met are overpayments.

(c) Once any group has chosen whether to use its fiscal year, the calendar year, or some other 12-month period, the group practice must adhere to this choice.

(d) The attestation must contain a statement that the information furnished in the attestation is true and accurate and must be signed by a group representative.

(e) A group that intends to meet the definition of a group practice in order to qualify for an exception described in §§ 411.355 through 411.357, must submit the attestation required by paragraph (a) or paragraph (b)(1) of this section, as applicable, to its carrier by December 12, 1995.

5. Section 411.361 is revised to read as follows:

§ 411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing items or services for which payment may be made under Medicare must submit information to HCFA concerning their financial relationships (as defined in paragraph (d) of this section), in such form, manner, and at such times as HCFA specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that provide 20 or fewer Part A and Part B items and services during a calendar year, or to designated health services provided outside the United States.

(c) *Required information.* The information submitted to HCFA under paragraph (a) of this section must include at least the following:

(1) The name and unique physician identification number (UPIN) of each physician who has a financial relationship with the entity;

(2) The name and UPIN of each physician who has an immediate relative (as defined in § 411.351) who has a financial relationship with the entity;

(3) The covered items and services provided by the entity; and

(4) With respect to each physician identified under paragraphs (c)(1) and (c)(2) of this section, the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement, if requested by HCFA).

(d) *Reportable financial relationships.* For purposes of this section, a financial relationship is any ownership or investment interest or any compensation arrangement, as described in section 1877 of the Act.

(e) *Form and timing of reports.* Entities that are subject to the requirements of this section must submit the required information on a HCFA-prescribed form within the time period specified by the servicing carrier or intermediary. Entities are given at least 30 days from the date of the carrier's or intermediary's request to provide the initial information. Thereafter, an entity must provide updated information within 60 days from the date of any change in the submitted information. Entities must retain documentation sufficient to verify the information provided on the forms and, upon request, must make that documentation available to HCFA or the OIG.

(f) *Consequences of failure to report.* Any person who is required, but fails, to submit information concerning his or her financial relationships in accordance with this section is subject to a civil money penalty of up to $10,000 for each day of the period beginning on the day following the applicable deadline established under paragraph (e) of this section until the information is submitted. Assessment of these penalties will comply with the applicable provisions of part 1003 of this title.

(g) *Public disclosure.* Information furnished to HCFA under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 16, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: May 10, 1995.

Donna E. Shalala,

Secretary.

[FR Doc. 95–19647 Filed 8–11–95; 8:45 am]

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federal register

Monday
August 14, 1995

Part III

Department of Health and Human Services

Food and Drug Administration

Order for Certain Class III Devices; Submission of Safety and Effectiveness Information; Notices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N–0418]

Order for Certain Class III Devices; Submission of Safety and Effectiveness Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order requiring manufacturers of 27 class III devices to submit to FDA a summary of, and a citation to, all information known or otherwise available to them respecting such devices, including adverse safety or effectiveness information concerning the devices which has not been submitted under the Federal Food, Drug, and Cosmetic Act (the act). FDA is requesting this information in order to determine, for each device, whether the classification of the device should be revised, or whether a regulation requiring the submission of premarket approval applications (PMA's) for the device should be promulgated. Based on preliminary information, FDA believes these 27 devices are not likely candidates for reclassification and, therefore, will likely require the submission of PMA's sometime in the future.

DATES: Summaries and citations must be submitted by the dates listed below.

ADDRESSES: Submit summaries and citations to the Documents Mail Center (HFZ–401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Melpomeni K. Jeffries, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the act (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. This notice refers to both the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date, as ''preamendments devices.''

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. However, submission of a PMA, or a notice of completion of a product development protocol (PDP), is not required until 90 days after FDA promulgates a final rule requiring premarket approval for the device, or 30 months after final classification of the device, whichever is later. Also, such a device is exempt from the investigational device exemption (IDE) regulations of 21 CFR part 812 until the date stipulated by FDA in the final rule requiring the submission of a PMA for that device. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations.

To date, FDA has issued final rules requiring the submission of PMA's for nine preamendment class III devices. Additionally, FDA has issued proposed rules for 10 other devices. There are 116 remaining preamendment class III devices for which FDA has not yet initiated action requiring the submission of PMA's.

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629) changed the definition of class II devices from those for which a performance standard is necessary to provide reasonable assurance of safety and effectiveness to those for which there is sufficient information to establish special controls to provide such assurance. Special controls include performance standards, postmarket surveillance, patient registries, guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)), recommendations, and other appropriate actions the agency deems necessary to provide such assurance. Thus, the SMDA modified the definition of class II devices to permit reliance on special controls, rather than performance standards alone, to provide reasonable assurance of safety and effectiveness.

The SMDA also added new section 515(i) (21 U.S.C. 360e(i)) to the act. This section requires FDA to order manufacturers of preamendment class III devices for which no final regulation has been issued requiring the submission of PMA's to submit to the agency a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information which has not been submitted under section 519 of the act (21 U.S.C. 360i). Section 519 of the act requires manufacturers, importers, or distributors to maintain records and to report information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury, or that a malfunction of the device is likely to cause death or serious injury on recurrence. Section 515(i) of the act also directs FDA to either revise the classification of the device into class I or class II or require the device to remain in class III; and, for devices remaining in class III, to establish a schedule for the promulgation of a rule requiring the submission of PMA's for the device.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA announced its strategy for addressing the remaining preamendment class III devices. In that notice, FDA made available a document setting forth its strategy for implementing the provisions of the SMDA which require FDA to review the classification of certain class III devices, and either reclassify them into class I or class II or retain them in class III. Pursuant to this plan, the agency divided the universe of preamendment class III devices into the following 3 groups: Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness, but are no longer used or are very limited in use. Group 2 devices are devices that FDA believes have a high potential for being reclassified into class II. Group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. There are a total of 43, 31, and 42 (15 high priority), devices in Groups 1, 2, and 3 respectively.

In the May 6, 1994, notice, FDA announced its intent to call for the submission of PMA's for the 15 highest priority devices in Group 3, and for all Group 1 devices. The agency also announced its intent to issue an order under section 515(i) of the act for the remaining Group 3 devices and all of the Group 2 devices. Under section 515(i) of the act, FDA is authorized to require the submission of the adverse safety and effectiveness information identified in the summary and citation submitted in response to this order, if such information is available. Based

upon the information submitted in response to this order, FDA will either propose reclassification of some or all of these devices into class I or class II, or propose retaining some or all of them in class III.

In this document, FDA is requiring manufacturers of 27 devices in Group 3 to submit a summary of, and citation to, all safety and effectiveness information known or otherwise available to them respecting such devices, including adverse information concerning the devices which has not been submitted under section 519 of the act. As noted above, based on information known to date by the agency, FDA believes these devices are not likely candidate for reclassification.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a similar notice covering the 31 Group 2 devices.

II. Statutory Authority and Enforcement

In addition to the provisions of section 515(i) of the SMDA described above, this order is issued under section 519 of the act, as implemented by § 860.7(g)(2) (21 CFR 860.7(g)(2)). This regulation authorizes FDA to require reports or other information bearing on the classification of a device. Section 519 of the act also requires the reporting of any death or serious injury caused by a device or by its malfunction.

Failure to furnish the information required by this order results in the device being misbranded under section 502(t) of the act (21 U.S.C. 352(t)) and is a prohibited act under sections 301(a) and (q) of the act (21 U.S.C. 331(a) and (q)). The agency will use its enforcement powers to deter noncompliance. Violations of section 301 of the act may be subject to seizure or injunction under sections 304(a) and 302(a) of the act (21 U.S.C. 334(a) and 332(a) respectively). In addition, violations under section 301 of the act may be subject to civil penalties under section 303(f) of the act (21 U.S.C. 333(f)), and criminal prosecution under section 303(a) of the act (21 U.S.C. 333(a)).

III. Order

The agency is hereby issuing this order under sections 515(i) and 519 of the act and § 860.7(g)(1) of the regulations. Under the order, the required information shall be submitted by the dates listed below so that FDA may begin promptly the process established by section 515(i) of the act to either revise or sustain the current classification of these devices.

A. Deadlines for Submission of Information

For the following nine devices, the required information shall be submitted by August 14, 1996.

1. § 868.2450 *Lung water monitor.*
2. § 868.2500 *Cutaneous oxygen monitor.*
3. § 868.5610 *Membrane lung for long-term pulmonary support.*
4. § 870.1025 *Arrhythmia detector and alarm.*
5. § 870.3300 *Arterial embolization device.*
6. § 870.3375 *Cardiovascular intravascular filter.*
7. § 874.3400 *Tinnitus masker.*
8. § 884.5940 *Powered vaginal muscle stimulator for therapeutic use.*
9. § 890.3890 *Stair-climbing wheelchair.*

For the following nine devices, the required information shall be submitted by February 14, 1997.

10. § 870.3610 *Implantable pacemaker pulse generator.*
11. § 870.3700 *Pacemaker programmers.*
12. § 870.3800 *Annuloplasty ring.*
13. § 870.4230 *Cardiopulmonary bypass defoamer.*
14. § 870.5225 *External counter-pulsating device.*
15. § 870.5550 *External transcutaneous cardiac pacemaker (noninvasive).*
16. § 874.3930 *Tympanostomy tube with semipermeable membrane.*
17. § 874.5350 *Suction antichoke device.*
18. § 886.3400 *Keratoprosthesis.*

For the following nine devices, the required information shall be submitted by August 14, 1997.

19. § 870.3450 *Vascular graft prosthesis of less than 6 millimeters diameter.*
20. § 870.3535 *Intra-aortic balloon and control system.*
21. § 870.3600 *External pacemaker pulse generator.*
22. § A874.5370 *Tongs antichoke device.*
23. § 876.5870 *Sorbent hemoperfusion system.*
24. § 876.5955 *Peritoneo-venous shunt.*
25. § 882.1790 *Ocular plethysmograph.*
26. § 882.5860 *Implanted neuromuscular stimulator.*
27. § 882.5950 *Artificial embolization device.*

B. Required Contents of Submissions

By the dates listed above, all manufacturers currently marketing preamendments class III devices subject to this order shall provide a summary of, and citation to, any information known or otherwise available to them respecting the devices, including adverse safety and effectiveness data which has not been submitted under section 519 of the act. FDA suggests that it may be in the best interest of submitters to summarize the information submitted under section 519 of the act to facilitate FDA's decisionmaking, even though such information is not required.

The information should be submitted in one of the two following formats depending on whether the applicant is aware of any information which would support the reclassification of the device into class I (general controls) or class II (special controls). Information which would support the reclassification of the device must consist of adequate, valid scientific evidence showing that general controls alone (class I), or general controls and special controls (class II) will provide a reasonable assurance of the safety and effectiveness of the device.

For manufacturers who do *not* believe that existing information would support the reclassification of their device into class I or class II, the information provided should be submitted in the following format:

1. *Indications for use.* A general description of the disease or condition to be diagnosed, treated, cured, mitigated, or prevented, including a description of the patient population for which the device is intended.
2. *Device description.* An explanation of how the device functions, significant physical and performance characteristics of the device, and basic scientific concepts that form the basis for the device.
3. *Other device labeling.* Other device labeling that includes contraindications, warnings and precautions and/or promotional materials.
4. *Risks.* A summary of all adverse safety and effectiveness information and identification of the risks presented by the device as well as any mechanisms or procedures which will control the risk.
5. *Alternative practices and procedures.* A description of alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended.
6. *Summary of preclinical and clinical data.* The summary of preclinical and clinical data should include the conclusions drawn from the studies which support the safety and effectiveness of the device as well as special controls, if any, which address

the adverse effects of the device on health. The summary should include a brief description of the objective of the studies, the experimental design, how the data were collected and analyzed, and a brief description of the results of the studies, whether positive, negative, or inconclusive. The summary of the clinical study(ies) should also include a discussion of the subject inclusion and exclusion criteria, the study population, reasons for patient discontinuations, and results of statistical analyses.

7. *Bibliography*. A copy of the key references, a brief summary of the salient features of each key reference, and a brief discussion of why the reference is relevant to an evaluation of the safety and effectiveness evaluation of the device.

Manufacturers who believe that existing information would support the reclassification of their device into class I or class II may either submit information using the format described below or may submit a formal reclassification petition, which should include the information described below in addition to the information required under 21 CFR 860.123.

1. *Identification*. A brief narrative identification of the device. This identification should be specific enough to distinguish a particular device from a generic type of device. Where appropriate, this identification should include a listing of the materials, and the component parts, and a description of the intended use of the device.

2. *Risks to health*. An identification of the risks to health should be provided. This section should summarize all adverse safety and effectiveness information, which have not been submitted under section 519 of the act particularly the most significant. The mechanisms or procedures which will control the risk should be described. A list of the general hazards associated with the device and a bibliography with copies of the referenced material should be provided.

3. *Recommendation*. A statement whether the manufacturer believes the device should be reclassified into class I or class II.

4. *Summary of reasons for recommendation*. Each manufacturer should include a summary of the reasons for requesting reclassification of its device and an explanation why it believes the device meets the statutory criteria for reclassification into class I or class II. Each manufacturer should also identify the special controls that it believes would be sufficient to provide reasonable assurance of the safety and effectiveness of its device if it believes the device should be reclassified into class II.

5. *Summary of valid scientific evidence on which the recommendation is based*. Manufacturers are advised that, when considering a formal reclassification petition, FDA will rely only upon valid scientific evidence to determine that there is a reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone (class I) or by general controls and special controls (class II). Valid scientific evidence consists of evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness. (See § 860.7(c)(2).)

According to § 860.7(d)(1) there is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions for use. Moreover, pursuant to § 860.7(e)(1), there is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

Manufacturers submitting a formal reclassification petition may wish to request two petitions as examples of successful reclassification petitions. Magnetic resonance imaging devices, Docket Nos. 87P–0214/CP through 87P–0215/CP0013, and Nd:YAG Laser for posterior capsulotomy devices, Docket No. 86P–0083, were both reclassified from class III to class II subsequent to the submission of a reclassification petition. Both petitions are available upon submission of a Freedom of Information request to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20850.

IV. Submission of Required Information

The summary of, and citation to, any information required by the act must be submitted by the dates listed above to the Document Mail Center (address above).

Dated: July 13, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95–19944 Filed 8–11–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94N–0417]

Order for Certain Class III Devices; Submission of Safety and Effectiveness Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order requiring manufacturers of 31 class III devices to submit to FDA a summary of, and a citation to, all information known or otherwise available to them respecting such devices, including adverse safety or effectiveness information concerning the devices which has not been submitted under the Federal Food, Drug, and Cosmetic Act (the act). FDA is requesting this information in order to determine, for each device, whether the classification of the device should be revised, or whether a regulation requiring the submission of premarket approval applications (PMA's) for the device should be promulgated. Based on preliminary information, FDA believes these 31 devices have a higher potential for reclassification.

DATES: Summaries and citations must be submitted by the dates listed below.

ADDRESSES: Submit summaries and citations to the Documents Mail Center (HFZ–401), Food and Drug Administration, Center for Devices and Radiological Health, 9200 Corporate Blvd., Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Melpomeni K. Jeffries, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the act (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. This notice refers to both the class III devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date, as ''preamendments devices.''

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. However, submission of a PMA, or a notice of completion of a product development protocol (PDP), is not required until 90 days after FDA promulgates a final rule requiring premarket approval for the device, or 30 months after final classification of the device, whichever is later. Also, such a device is exempt from the investigational device exemption (IDE) regulations of part 812 (21 CFR part 812) until the date stipulated by FDA in the final rule requiring premarket approval for that device. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed only for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations.

To date, FDA has issued final rules requiring the submission of PMA's for nine preamendment class III devices. Additionally, FDA has issued proposed rules for 10 other devices. There are 116 remaining preamendment class III devices for which FDA has not yet initiated action requiring the submission of PMA's.

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629) changed the definition of class II devices from those for which a performance standard is necessary to provide reasonable assurance of safety and effectiveness to those for which there is sufficient information to establish special controls to provide such assurance. Special controls include performance standards, postmarket surveillance, patient registries, guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)), recommendations, and other appropriate actions the agency deems necessary to provide such assurance. Thus, the SMDA modified the definition of class II devices to permit reliance on special controls, rather than performance standards alone, to provide reasonable assurance of safety and effectiveness.

The SMDA also added new section 515(i) (21 U.S.C. 360e(i)) to the act. This section requires FDA to order manufacturers of preamendment class III devices for which no final regulation has been issued requiring the submission of PMA's to submit to the agency a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information which has not been submitted under section 519 of the act (21 U.S.C. 360i). Section 519 of the act (21 U.S.C. 360i) requires manufacturers, importers, or distributors to maintain records and to report information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury or that a malfunction of the device is likely to cause death or serious injury on recurrence. Section 515(i) of the act also directs FDA to either revise the classification of the device into class I or class II or require the device to remain in class III; and for devices remaining in class III, to establish a schedule for the promulgation of a rule requiring the submission of PMA's for the device.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA announced its strategy for addressing the remaining preamendment class III devices. In that notice, FDA made available a document setting forth its strategy for implementing the provisions of the SMDA which require FDA to review the classification of certain class III devices, and either reclassify them into class I or class II or retain them in class III. Pursuant to this plan, the agency divided the universe of preamendment class III devices into the following 3 groups. Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness, but are no longer used or are very limited in use. Group 2 devices are devices that FDA believes have a high potential for being reclassified into class II. Group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. There are a total of 43, 31, and 42 (15 high priority) devices in Groups 1, 2, and 3, respectively.

In the May 6, 1994 notice, FDA announced its intent to call for the submission of PMA's for the 15 highest priority devices in Group 3 and for all Group 1 devices. The agency also announced its intent to issue an order under section 515(i) of the act for the remaining Group 3 devices and all of the Group 2 devices. Under section 515(i) of the act, FDA is authorized to require the submission of the adverse safety and effectiveness information identified in the summary and citation submitted in response to this order, if such information is available. Based upon the information submitted in response to this order, FDA will either propose reclassification of some or all of these devices into class I or class II, or propose retaining some or all of them in class III.

In this document, FDA is requiring manufacturers of all 31 devices in Group 2 to submit a summary of, and citation to, all safety and effectiveness information known or otherwise available to them respecting such devices, including adverse information concerning the devices which has not been submitted under section 519 of the act. As noted above, FDA believes that these devices have a higher potential for reclassification provided that manufacturers collect, analyze, and submit the necessary supporting information in response to this notice.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a similar notice with respect to the 27 remaining Group 3 devices.

II. Statutory Authority and Enforcement

In addition to the provisions of section 515(i) of the SMDA described above, this order is issued under section 519 of the act, as implemented by § 860.7(g)(2) (21 CFR 860.7(g)(2)). This regulation authorizes FDA to require reports or other information bearing on the classification of a device. Section 519 of the act also requires the reporting of any death or serious injury caused by a device or by its malfunction.

Failure to furnish the information required by this order results in the device being misbranded under section 502(t) of the act (21 U.S.C. 352 (t)) and is a prohibited act under sections 301(a) and (q) of the act (21 U.S.C. 331(a) and (q)). The agency will use its enforcement

powers to deter noncompliance. Violations of section 301 of the act may be subject to seizure or injunction under sections 304(a) and 302(a) of the act (21 U.S.C. 334(a) and 332(a) respectively). In addition, violations under section 301 of the act may be subject to civil penalties under section 303(f) of the act (21 U.S.C. 333(f)) and criminal prosecution under section 303(a) of the act (21 U.S.C. 333(a)).

III. Order

The agency is hereby issuing this order under sections 515(i) and 519 of the act and § 860.7(g)(1) of the regulations. Under the order, the required information shall be submitted by the dates listed below so that FDA may begin promptly the process established by section 515(i) of the act to either revise or sustain the current classification of these devices.

A. Deadlines for Submission of Information

For the following 8 devices, the required information shall be submitted by August 14, 1996.

1. § 864.7250 *Erythropoietin assay.*
2. § 864.7300 *Fibrin monomer paracoagulation test.*
3. § 876.3630 *Penile rigidity implant.*
4. § 878.5360 *Tweezer-type epilator.*
5. § 884.1060 *Endometrial aspirator.*
6. § 884.1100 *Endometrial brush.*
7. § 884.1185 *Endometrial washer.*
8. § 886.3920 *Eye valve implant.*

For the following 9 devices, the required information shall be submitted by February 14, 1997.

9. § 866.3305 *Herpes simplex virus serological reagents.*
10. § 866.3510 *Rubella virus serological reagents.*
11. § 870.3620 *Pacemaker lead adaptor.*
12. § 872.6080 *Airbrush.*
13. § 876.4480 *Electrohydraulic lithotriptor.*
14. § 878.3610 *Esophageal prosthesis.*
15. § 878.3720 *Tracheal prosthesis.*
16. § 884.4100 *Endoscopic electrocautery and accessories.*
17. § 884.4150 *Bipolar endoscopic coagulator-cutter and accessories .*

For the following 10 devices, the required information shall be submitted by August 14, 1997.

18. § 868.1150 *Indwelling blood carbon dioxide partial pressure (Pco2) analyzer.*
19. § 868.1170 *Indwelling blood hydrogen ion concentration (pH) analyzer.*
20. § 868.1200 *Indwelling blood oxygen partial pressure (Pco2) analyzer.*
21. § 870.3680(b) *Cardiovascular permanent pacemaker electrode.*
22. § 870.4260 *Cardiopulmonary bypass arterial line blood filter.*
23. § 870.4350 *Cardiopulmonary bypass oxygenator.*
24. § 876.5860 *High permeability hemodialysis system.*
25. § 878.5650 *Topical oxygen chamber for extremities.*
26. § 882.5940 *Electroconvulsive therapy device.*
27. § 888.3660 *Shoulder joint metal/polymer semi-constrained cemented prosthesis.*

For the following 4 devices, the required information shall be submitted by August 14, 1998.

28. § 870.3710 *Pacemaker repair or replacement material.*
29. § 870.4320 *Cardiopulmonary bypass pulsatile flow generator.*
30. § 870.5200 *External cardiac compressor.*
31. § 876.5540(b)(1) *Implanted blood access device.*

B. Required Contents of Submissions

By the dates listed above, all manufacturers currently marketing preamendments class III devices subject to this order shall provide a summary of, and citation to, any information known or otherwise available to them respecting the devices, including adverse safety and effectiveness data which has not been submitted under section 519 of the act. FDA suggests that it may be in the best interest of submitters to summarize the information submitted under section 519 of the act to facilitate FDA's decision making, even though such information is not required.

The information should be submitted in one of the two following formats depending on whether the applicant is aware of any information which would support the reclassification of the device into class I (general controls) or class II (special controls). Information which would support the reclassification of the device must consist of adequate, valid scientific evidence showing that general controls alone (class I), or general controls and special controls (class II) will provide a reasonable assurance of the safety and effectiveness of the device.

For manufacturers who do *not* believe that existing information would support the reclassification of their device into class I or class II, the information provided should be submitted in the following format:

1. *Indications for use.* A general description of the disease or condition to be diagnosed, treated, cured, mitigated, or prevented, including a description of the patient population for which the device is intended.

2. *Device description.* An explanation of how the device functions, significant physical and performance characteristics of the device, and basic scientific concepts that form the basis for the device.

3. *Other device labeling.* Other device labeling that includes contraindications, warnings and precautions and/or promotional materials.

4. *Risks.* A summary of all adverse safety and effectiveness information and identification of the risks presented by the device as well as any mechanisms or procedures which will control the risk.

5. *Alternative practices and procedures.* A description of alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended.

6. *Summary of preclinical and clinical data.* The summary of preclinical and clinical data should include the conclusions drawn from the studies which support the safety and effectiveness of the device as well as special controls, if any, which address the adverse effects of the device on health. The summary should include a brief description of the objective of the studies, the experimental design, how the data were collected and analyzed, and a brief description of the results of the studies, whether positive, negative, or inconclusive. The summary of the clinical study(ies) should also include a discussion of the subject inclusion and exclusion criteria, the study population, reasons for patient discontinuations, and results of statistical analyses.

7. *Bibliography.* A copy of the key references, a brief summary of the salient features of each key reference, and a brief discussion of why the reference is relevant to an evaluation of the safety and effectiveness evaluation of the device.

Manufacturers who believe that existing information would support the reclassification of their device into class I or class II may either submit information using the format described below or may submit a formal reclassification petition, which should include the information described below in addition to the information required under 21 CFR 860.123.

1. *Identification.* A brief narrative identification of the device. This identification should be specific enough to distinguish a particular device from a generic type of device. Where appropriate, this identification should include a listing of the materials, and the component parts, and a description of the intended use of the device.

2. *Risks to health*. An identification of the risks to health should be provided. This section should summarize all adverse safety and effectiveness information, which have not been submitted under section 519 of the act, particularly the most significant. The mechanisms or procedures which will control the risk should be described. A list of the general hazards associated with the device and a bibliography with copies of the referenced material should be provided.

3. *Recommendation*. A statement whether the manufacturer believes the device should be reclassified into class I or class II.

4. *Summary of reasons for recommendation*. Each manufacturer should include a summary of the reasons for requesting reclassification of its device and an explanation why it believes the device meets the statutory criteria for reclassification into class I or class II. Each manufacturer should also identify the special controls that it believes would be sufficient to provide reasonable assurance of the safety and effectiveness of its device if it believes the device should be reclassified into class II.

5. *Summary of valid scientific evidence on which the recommendation is based*. Manufacturers are advised that, when considering a formal reclassification petition, FDA will rely only upon valid scientific evidence to determine that there is reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone (class I) or by general controls and special controls (class II). Valid scientific evidence consists of evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness. (See § 860.7(c)(2).)

According to § 860.7(d)(1) there is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions for use. Moreover, pursuant to § 860.7(e)(1), there is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

Manufacturers submitting a formal reclassification petition may wish to request two petitions as examples of successful reclassification petitions. Magnetic resonance imaging devices, Docket Nos. 87P–0214/CP through 87P–0215/CP0013, and Nd:YAG Laser for posterior capsulotomy devices, Docket No. 86P–0083, were both reclassified from class III to class II subsequent to the submission of a reclassification petition. Both petitions are available upon submission of a Freedom of Information request to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20850.

IV. Submission of Required Information

The summary of, and citation to, any information required by the act must be submitted by the dates listed above to the Document Mail Center (address above).

Dated: July 13, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95–19945 Filed 8–11–95; 8:45 am]

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federal register

Monday
August 14, 1995

Part IV

Department of Transportation

Federal Aviation Administration

14 CFR Part 121 et al.

Operational and Structural Difficulty Reports; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 121, 125, 127, 135, and 145

[Docket No. 28293; Notice No. 95–12]

RIN: 2120–AF71

Operational and Structural Difficulty Reports

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Aviation Administration (FAA) proposes to revise the reporting requirements for air carrier certificate holders and certificated domestic and foreign repair stations concerning failures, malfunctions, and defects of aircraft, aircraft engines, systems, and components. The proposed rule would clarify and standardize the type of information submitted to the FAA allowing the FAA to identify trends that may affect aviation safety. This action was prompted by an internal FAA review of the effectiveness of the reporting system and by air carrier industry concern over the quality of the data being reported by air carriers. The objective of the proposed rule is to update and improve the reporting system to effectively collect and disseminate clear and concise information, particularly with regard to aging aircraft, to the aviation industry.

DATES: Comments must be submitted on or before November 13, 1995.

ADDRESSES: Comments on this notice should be delivered, in triplicate, to: Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket (AGC–200), Docket No. 28293, 800 Independence Avenue SW., Washington, DC 20591. Comments delivered must be marked Docket No. 28293. Comments may also be submitted electronically to the following Internet address: nprmcmts@mail.hq.faa.gov. Comments may be examined in Room 915G weekdays between 8:30 a.m. and 5 p.m., except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: Benjamin J. Burton, Aircraft Maintenance Division, AFS–330, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, telephone (202) 267–3797.

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. Comments relating to the environmental, energy, federalism, or economic impact that might result from adopting the proposals in this notice are also invited. Substantive comments should be accompanied by cost estimates. Comments should identify the regulatory docket or notice number and should be submitted in triplicate to the Rules Docket address specified above. All comments received on or before the closing date for comments specified will be considered by the Administrator before taking action on this proposed rulemaking. The proposals contained in this notice may be changed in light of comments received. All comments received 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 substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must include a preaddressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 28293.'' The postcard will be date stamped and mailed to the commenter.

Availability of the NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–220, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–3484.

Persons interested in being placed on the mailing list for future NPRMs should request from the above office a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Background

Sections 121.703, 127.313, and 135.515 require that holders of certificates issued under part 121, 127, or 135 submit reports on certain specified failures, malfunctions, or defects of specific systems and on all other failures, malfunctions, or defects that, in the opinion of the certificate holder, have endangered or may endanger the safe operation of an aircraft. Section 125.409 requires that part 125 certificate holders report each failure, malfunction, or defect. In addition, §§ 145.63 and 245.79 contain provisions for certificated domestic and foreign repair stations, respectively, to report defects or recurring unairworthy conditions of any aircraft, powerplant, propeller, or any component thereof to the FAA. Both certificate holders and certificated repair stations must submit the reports described above to the FAA. In accordance with the Flight Standards' Service Difficulty Program, set forth in FAA Order No. 8010.2, the information is reviewed and evaluated by the Principal Maintenance Inspector (PMI) and mailed to the FAA's Mike Monroney Aeronautical Center in Oklahoma City, OK, for input into the Service Difficulty Reporting Subsystem (SDRS). The report data is entered into the SDRS and compiled to generate a weekly summary that is distributed to aircraft manufacturers, air carriers, repair stations, members of the general aviation community, and various offices of the FAA. Additional review and evaluation of the data are accomplished by the Aeronautical Center to identify trends or significant reports. The appropriate FAA office is notified if trends or significant safety items are noted.

Sections 121.705, 127.315, and 135.417 contain provisions for submitting a summary report to the FAA on mechanical difficulties or malfunctions that interrupt a flight or cause unscheduled aircraft changes, stops, or diversions en route that are not required to be reported under § 121.703, 127.313, or 135.415, respectively. Section 121.705 also requires a summary report containing information on the number of aircraft engines removed prematurely because of a malfunction, failure, or defect and the number of propeller featherings that occur in flight for other than training purposes, demonstrations, or flight checks.

Section 127.315 requires further summary reports containing information on the number of engines removed, and § 135.417 requires further summary reports on the number of propeller featherings that occur.

The reporting requirements for § 21.3 have not been addressed in this notice. ARAC decided and FAA agreed that revisions to this section were not intended as part of the FAA's original task assignment to ARAC.

History

The explosive decompression and structural failure of a Boeing 737–200 series aircraft on April 28, 1988, focused

worldwide attention on aging air carrier fleets. As a result of this event, a joint effort between the air carrier industry and regulatory authorities was established to address the continued airworthiness of the air transport fleet. This effort led to the establishment of the Airworthiness Assurance Task Force (AATF).

The AATF's activities focused on five major efforts that were a direct result of airworthiness issues presented by airlines and aircraft manufacturers at the First International Conference on Aging Airplanes, which was hosted by the FAA in June 1988. One of the issues presented at the conference was the need to ensure an adequate communications system between airlines, manufacturers, and the FAA. This task was assigned to the Improved Airworthiness Communications Steering Committee (IACSC) Data Collection Subcommittee of the AATF.

The FAA attended joint FAA/industry meetings with the IACSC to discuss problems associated with §§ 121.703, 121.705, 145.63, 145.79, and the Service Difficulty Report (SDR) program. Issues addressed in the March 21, 1991, General Accounting Office (GAO) report entitled *Changes Needed in FAA 's Service Difficulty Reporting Program* and written proposals from IACSC surfaced as points of discussion during the FAA/industry meetings. Members of the air carrier industry and FAA personnel expressed concern that, because of a lack of a standardized reporting format, there are varied interpretations of what is required to be reported. It was also noted that report information submitted by air carriers is inconsistent from airline to airline and results in incomplete data. In addition, air carriers voiced concern about the timeliness of the FAA's dissemination of SDR information. The IACSC noted that the manual data entry of reports into the SDRS delays the distribution of information to the airlines.

The IACSC recommended establishing a new § 121.704. This new section specifically would address defects in aircraft structures and problems normally associated with aging aircraft. The IACSC further suggested that the reporting requirements of §§ 121.703(a)(14) and 121.703(a)(15) relating to aircraft structures be revised and transferred to the proposed new section. The proposed reporting requirements would enable collection of information on discrepancies found in primary structure or principal structural elements. In addition, information on discrepancies found in composite materials that comprise primary structure or principal structural elements would be collected.

The IACSC also suggested revising §§ 145.63 and 145.79 to allow part 121 certificate holders to require certificated repair stations to submit the reports required under proposed §§ 121.703 and 121.704 when a repair station discovers a malfunction or defect in a certificate holder's aircraft. This change would serve to reduce the number of duplicate reports on the same problem from air carriers and repair stations, who presently are both required to report the occurrence.

The IACSC was realigned as the International Airworthiness Communications Working Group (IACWG) under the Aviation Rulemaking Advisory Committee (ARAC). The ARAC was established under FAA Order No. 1110.119, dated February 22, 1991, to advise the FAA on aviation safety-related rulemaking activity on a wide range of issues. Following the evaluation of the IACWG's recommendation for the revision of part 121, the ARAC tasked the group with preparing similar recommendations for operations conducted under parts 125, 127, and 135.

During preparation of the recommendations for parts 125, 127, and 135, the IACWG noted that the current reliability reporting requirements of §§ 127.315 and 135.417 are also unnecessary. There is no equivalent section in part 125. Therefore, the IACWG suggested deleting §§ 127.315 and 135.417, which would be consistent with the IACWG's proposed deletion of § 121.705. Currently, reliability information for operations conducted under these parts must be monitored in accordance with §§ 127.136 and 135.431.

The IACSC also was of the opinion that the current reporting requirements of § 121.705 are unnecessary because the data reported is reliability information that does not affect flight safety. The subcommittee further stated that this regulation does not provide sufficient guidance on the type or scope of the information to be reported; therefore, reporting is inconsistent. Reliability information currently must be monitored in accordance with § 121.373. Consequently, IACSC did not believe § 121.705 was necessary and suggested that it be deleted.

Subsequent discussions within the working group revealed that § 121.705(a) would need to remain in the regulation so that PMI's would continue to receive timely information from air carriers on mechanical interruptions of flights caused by malfunctions or defects that are not required to be reported to the SDRS. The working group, therefore, recommended deleting only §§ 121.705 (b) and (c), 127.315(b), and 135.417(b), which relate to premature engine removals and in-flight propeller featherings.

The Proposed Rule

Based on the earlier joint discussions with representatives of the air carrier industry, recommendations from the ARAC, and an internal review of the SDR program, the FAA recognizes that improvements to reporting requirements and the SDR program are necessary. This proposed rule presents actions to correct deficiencies cited during the FAA/industry meetings and in the GAO report, and was developed based on the recommendations from the ARAC.

This proposed rule would modify the current reporting requirements for air carriers and repair stations to standardize report information. The proposed rule also would explicitly permit the submission of the required reports in an electronic form to encourage reporting that will give the FAA information on a near real-time basis. In addition, the proposed rule would revise the current reporting requirements for air carriers to include the reporting of certain occurrences or detections of failures, malfunctions, or defects of aircraft, aircraft engines, systems, and components that occur during ground operations and that could affect the safety of flight operations.

The proposed rule would also allow part 121, 125, 127, or 135 certificate holders to require a certificated domestic or foreign repair station to submit operational and structural difficulty reports to the FAA on behalf of the certificate holder when the repair station discovers defects or unairworthy conditions. This provision would eliminate duplicate reporting of a problem by the air carrier and the repair station. The proposed rule would delete §§ 121.705 (b) and (c), 127.315(b), and 135.417(b), removing the requirement for submitting summary reports on premature engine removals and in-flight propeller featherings because this information is reliability-related data rather than safety-of-flight data. The proposed rule also would add new §§ 121.704, 125.410, 127.314, and 135.416 to specifically address the reporting of structural defects and problems normally associated with aging aircraft.

Sections 121.703, 125.409, 127.313, and 135.415 would be revised to focus on the reporting of operational defects, and new §§ 121.704, 125.410, 127.314,

and 135.416 would be added to manage the reporting of structural defects.

Section 125.409 would be revised by requiring reports for specific events rather than reports of the occurrence or detection of every failure, malfunction, or defect. The proposed change eliminates the reporting of defects that do not compromise the airworthiness of the aircraft. The proposal would add requirements to part 125 that are equivalent to the reporting requirements in proposed §§ 121.703, 127.313, and 135.415.

In proposing to revise the part 135 reporting requirements, the FAA recognizes that aircraft maintained in accordance with part 135 may operate under part 91 at times; however, all part 135 reporting requirements would apply as long as the aircraft is maintained under part 135.

Reporting requirements would be revised for each of the proposed sections to standardize report information. Required reporting information would be revised to include total aircraft flight time to aid in evaluating corrosion and aircraft structural fatigue. In addition, the amount of elapsed time since the last maintenance performed on components would be added to determine how long components have been in service. Information on manufacturer's part numbers and serial numbers would be added to develop trend information. Reporting procedures would also be revised to encourage the electronic transmission of data directly to a centralized collection point as specified by the FAA. (Presently, the data base is maintained at the Mike Monroney Aeronautical Center.) A program that enters SDR data electronically into the SDRS would be optional. The electronic submission of data would provide a database that is near real-time. Data would be uploaded and available the next business day. The proposed rule would also provide for collecting information on aborted or ''rejected'' takeoffs caused by the failure, malfunction, or defect of an aircraft component or system. This information would be used to generate statistical data for future analysis of the safety implications such events may have on flight operations.

Sections 145.63 and 145.79 would be revised to allow parts 121, 125, 127, and 135 certificate holders to require certificated domestic and foreign repair stations to submit the reports required under the proposed sections of parts 121, 125, 127, and 135 on behalf of the certificate holder when the repair station discovers a malfunction or defect. This proposed change would eliminate the requirement for the air carrier and the repair station to report the same problem to the FAA. However, the air carrier would not be relieved of the responsibility of ensuring that these reports are submitted.

The purpose of the proposed regulation would be to enhance air carrier safety by collecting additional and more timely data that identifies mechanical failures, malfunctions, and defects which may be a serious hazard to the operation of an aircraft. The information collected would be used to develop and implement corrective actions to help prevent future occurrences of these failures, malfunctions, and defects once they have been identified.

It should be noted that there is currently a proposal to delete part 127 in an NPRM published in the **Federal Register** on March 29, 1995, regarding Commuter Operations and General Certification and Operations Requirements (60 FR 16230). If part 127 is deleted in that final rule as proposed, the proposed revisions to part 127 in this NPRM will not be considered in the development of a final rule.

General Discussion of the Proposed Rule

Sections 121.703, 125.409, 127.313, and 135.415

The proposed rule would change the titles of §§ 121.703, 127.313, and 135.415 from ''Mechanical reliability reports'' to ''Operational difficulty reports.'' The proposed rule also would change the title of § 125.409 from ''Reports of defects or unairworthy conditions'' to ''Operational difficulty reports.'' The title change would reflect more accurately the type of information collected, which may be categorized as primarily operational and safety-related information rather than reliability and failure information as is implied by the current titles.

Sections 121.703(a)(1), 125.409(a)(1), 127.313(a)(1), and 135.415(a)(1)

Proposed §§ 121.703(a)(1), 125.409(a)(1), 127.313(a)(1), and 135.415(a)(1) would specify that a certificate holder must report each failure, malfunction, or defect involving any fire, rather than only those fires that occur during flight, as is currently prescribed by the regulations. The proposed changes would ensure that information is also reported on fires that occur on the ground because these fires may affect the safety of flight. In addition, the current requirement to report whether the related fire-warning system functioned properly in the event of a fire caused by a failure, malfunction, or defect also would be retained by the proposed rule.

Current §§ 121.703(a)(2), 127.313(a)(2), and 135.415(a)(2) require certificate holders to report failures, malfunctions, or defects concerning fires during flight that are not protected by a related fire warning system. Proposed §§ 121.703(a)(1), 125.409(a)(1), 127.313(a)(1), and 135.415(a)(1) would retain this requirement because failures, malfunctions, or defects involving any fire must be reported by the certificate holder.

Sections 121.703(a)(2), 125.409(a)(2), 127.313(a)(2), and 135.415(a)(2)

Proposed §§ 121.703(a)(2), 127.313(a)(2), and 135.415(a)(2) would revise current §§ 121.703(a)(3), 127.313(a)(3), and 135.415(a)(3), respectively, which address the reporting of failures, malfunctions, or defects involving false fire warnings during flight. The proposed rule would require that any false fire or smoke warning necessitating the use of emergency procedures be reported to ensure that the certificate holder documents occurrences that have safety-of-flight implications. This requirement also would be added to proposed § 125.409(a)(2).

Sections 121.703(a)(3), 125.409(a)(3), 127.313(a)(3), and 135.415(a)(3)

Proposed §§ 121.703(a)(3), 127.313(a)(3), and 135.415(a)(3) would require that information on damage to an engine, adjacent structure, equipment, or components caused by a failure, malfunction, or defect of an engine exhaust system be reported by the certificate holder regardless of whether such damage occurred in flight or on the ground. Proposed § 125.409(a)(3) would add the same requirements for operations conducted under part 125. Currently, §§ 121.703(a)(4), 127.313(a)(4), and 135.415(a)(4) require only that the certificate holder report to the FAA damage to an engine, adjacent structure, equipment, or components caused by an engine exhaust system during flight.

Sections 121.703(a)(4), 125.409(a)(4), 127.313(a)(4), and 135.415(a)(4)

Proposed §§ 121.703(a)(4), 127.313(a)(4), and 135.415(a)(4) would revise the current requirements in §§ 121.703(a)(5), 127.313(a)(5), and 135.415(a)(5), respectively, by requiring that the failure, malfunction, or defect of airplane or helicopter components that cause an accumulation or circulation of smoke, vapor, or toxic or noxious fumes resulting in the use of emergency

procedures be reported. Proposed § 125.409(a)(4) would add the same requirements for operations conducted under part 125. These proposed changes would eliminate the reporting of events that do not affect safety by indicating that such events would have to be reported only if emergency procedures are exercised.

The proposed change also would delete the words ''during flight.'' The proposed reporting requirement would include events that occur in flight or on the ground and would expand the reporting of these events to the entire aircraft. The current requirements only cover these events if they occur in the crew compartment or passenger cabin.

Sections 121.703(a)(5), 125.409(a)(5), 127.313(a)(5), and 135.415(a)(5)

These proposed sections would combine the reporting requirements for engine failures and shutdowns in current §§ 121.703(a)(6), 121.703(a)(7), 121.703(a)(8), and 121.703(a)(9) into proposed § 121.703(a)(5); current §§ 127.313(a)(6), 127.313(a)(7), 127.313(a)(8), and 127.313(a)(9) into proposed § 127.313(a)(5); and current §§ 135.415(a)(6), 135.415(a)(7), 135.415(a)(8), and 135.415(a)(9) into proposed § 135.415(a)(5). An equivalent § 125.409(a)(5) would also be added.

The proposed change would require that the certificate holder report failures, malfunction, or defects involving all engine flameouts and shutdowns during ground or flight operations. The proposed sections would contain a provision to exclude intentional engine shutdowns, such as those that occur during flight crew training, test flights, and taxiing to reduce fuel consumption.

Sections 121.703(a)(6), 125.409(a)(6), and 135.415(a)(6)

These proposed sections would amend current §§ 121.703(a)(10) and 135.415(a)(10) by deleting the words ''during flight.'' The proposed change would require that the certificate holder report the failure, malfunction, or defect of any propeller feathering system or the ability of the system to control overspeed events whether such events occur during flight or on the ground. Proposed § 125.409(a)(6) would specifically state the equivalent requirement for operations conducted under part 125.

Sections 121.703(a)(7), 125.409(a)(7), 127.313(a)(6), and 135.415(a)(7)

These proposed paragraphs would redesignate the requirements in § 121.703(a)(11) as § 121.703(a)(7), § 127.313(a)(9) as § 127.313(a)(6), and § 135.415(a)(11) as § 135.415(a)(7), and would add new §§ 125.409(a)(7). These requirements pertain to reporting the failure, malfunction, or defect of a fuel or fuel-dumping system that affects fuel flow or causes hazardous leakage in flight. Section 127.313(a)(6) is proposed to include fuel dumping systems because these systems are now available on some helicopters.

Sections 121.703(a)(8), 125.409(a)(8), 127.313(a)(10), and 135.415(a)(8)

The proposed rule would redesignate current paragraph § 121.703(a)(12) as § 121.703(a)(8); revise current § 135.415(a)(12) and redesignate it as § 135.415(a)(8); revise § 127.313(a)(10); and add new § 125.409(a)(8). These sections require the reporting of failures, malfunctions, or defects in the operation of landing gear and landing gear doors during flight. Section 127.313(a)(10) would be revised to include equivalent requirements to apply to helicopters that have retractable landing gear. The requirements of current § 127.313(a)(10) related to helicopter structures that require major repairs would be moved to proposed new § 127.314. The proposed rule would also remove the term ''unwanted'' from current § 135.415(a)(12) to require that any landing gear extension or retraction, or opening or closing of landing gear doors during flight resulting from a malfunction or defect must be reported. This also would ensure consistency with the reporting requirements of parts 121 and 125.

Sections 121.703(a)(9), 125.409(a)(9), 127.313(a)(11), and 135.415(a)(9)

Current §§ 121.703(a)(13) and 135.415(a)(13) relating to failures, malfunctions, or defects in aircraft braking components would be revised and redesignated as proposed §§ 121.703(a)(9) and 135.415(a)(9), respectively. The equivalent requirements would be revised and redesignated in proposed § 125.409(a)(9) to provide consistency with parts 121 and 135. Section 127.313(a)(11) would be revised to include the reporting of failures, malfunctions, or defects of brake system components because wheeled helicopters are equipped with brakes. The requirements of current § 127.313(a)(11) related to cracks, deformation, or corrosion of helicopter structures would be moved to proposed new § 127.314.

The proposed rule would change ''loss of brake actuating force'' to ''any detectable loss of brake actuating force'' to clarify the interpretation of the term ''loss.'' Some air carriers have interpreted the term ''loss'' to mean total loss of braking action. This proposed rule would state that failures, malfunctions, or defects that result in any reduced braking are events that are required to be reported, excluding aircraft braking component malfunctions, defects, or discrepancies that are deferrable according to the Minimum Equipment List as provided for in § 91.213.

Sections 121.703(a)(10), 125.409(a)(10), 127.313(a)(7), and 135.415(a)(10)

Proposed §§ 121.703(a)(10), 125.409(a)(10), 127.313(a)(7), and 135.415(a)(10) would include the reporting of information relating to aborted takeoff. Currently, air carriers are not required to report information on aborted or ''rejected'' takeoffs. Limited information relating to aborted takeoffs that result from an accident or incident may be available through the FAA's Accident/Incident Data Subsystem or the National Transportation Safety Board (NTSB). The proposed rule would require that information on all aborted takeoffs after initiation of the takeoff roll, resulting from a failure, malfunction, or defect of an aircraft component or system be reported to troubleshoot problems that may have safety-of-flight implications.

In addition, the current regulations require reporting of failures, malfunctions, or defects occurring in aircraft components or systems that result in any emergency action taken during flight, excluding the shutdown of an aircraft engine. The reference to excepting engine shutdowns in current §§ 121.703(a)(16), 127.313(a)(12), and 135.415(a)(16) would not be included in this proposed paragraph because the reporting of failures, malfunctions, or defects involving any aircraft engine shutdown would be required by proposed §§ 121.703(a)(5), 127.313(a)(5), and 135.415(a)(5), respectively.

Sections 121.703(a)(11), 125.409(a)(11), 127.313(a)(9), and 135.415(a)(11)

The proposed paragraphs would revise current § 121.703(a)(17) and redesignate it as § 121.703(a)(11); add new § 125.409(a)(11); and revise current §§ 127.313(a)(9) and 135.415(a)(11). The proposed rule would state that a failure of individual components that does not affect the operation of an aircraft's emergency evacuation system or components, exit doors, passenger evacuation lighting systems, or evacuation equipment need not be reported. The proposed rule also would state that failures, malfunctions, or defects that are deferrable according to the Minimum Equipment List as provided for in § 91.213 need not be reported. This proposed change would

allow the exclusion of an item failure, such as a burned out reading light bulb, provided that such a failure would not affect the integrity of any of the systems and components described above.

Sections 121.703(c), 125.409(c), 127.313(c), and 135.415(c)

The proposed rule would revise current §§ 121.703(c), 127.313(c), and 135.415(c), and would add new § 125.409(c). These sections would extend the reporting requirements of a failure, malfunction, or defect in any aircraft to the aircraft, aircraft systems, components, and powerplants. These items have been added to require that reports of failures, malfunctions, or defects that endanger safe aircraft operation must include those that occurred throughout the aircraft as well as all of those that involve the aircraft's subassemblies.

Sections 121.703(d), 125.409(d), 127.313(d), and 135.415(d)

Under the proposed rule, each report of the occurrence or detection of a failure or defect for a 24-hour period still would be required to be submitted within 72 hours. However, this proposed rule would revise the current requirements in §§ 121.703(d), 127.313(d), and 135.415(d) by replacing the terms ''send,'' ''mailed,'' or ''delivered'' with the term ''submit.'' An equivalent § 125.409(d) would also be added that revises the reporting requirements currently found in § 125.409(b). This change would allow for the use of other means, such as electronic transmission via telephone facsimile or computer modem, to submit reports to the FAA. In addition, these proposed sections would change the location for submitting reports from the FAA Flight Standards District Office (FSDO) charged with the overall inspection of the certificate holder to a centralized collection point as specified by the FAA. However, the certificate holder would be required to make the operational difficulty report (ODR) data available to the FSO for examination at the time it is submitted to the FAA in a form and manner acceptable to the Administrator. This change would allow PMI's to remain informed of ODR activity and improve the timeliness of FAA processing of the data.

Currently, § 135.415(d) contains provisions for aircraft operating in areas where mail is not collected, thereby preventing mailing within the required 72 hours. In such cases, the reports are required to be submitted within 24 hours after the aircraft returns to a point where mail is collected. This provision also would be included in proposed § 125.409(d) because part 125 certificate holders often have remote operations similar to certain part 135 certificate holders.

Sections 121.703(e), 125.409(e), 127.313(e), and 135.415(e)

These proposed sections would revise the current reporting requirements of §§ 121.703(e), 127.313(e), and 135.415(e), and would add new reporting requirements in proposed § 125.409(e) to ensure reporting consistency. Current requirements of §§ 121.703(e), 127.313(e), and 135.415(e) allow the certificate holder to submit reports in a manner and form convenient to the certificate holder. The proposed changes would standardize reporting requirements and would explicitly provide for electronic reporting.

Section 121.703(e) specifies that information detailed in paragraphs (e)(1) through (e)(6) is mandatory and that information detailed in paragraphs (e)(7) through (e)(9) is desirable additional information. Additional available information may be submitted at a later date by resubmitting the ODR under its original Operator Control number as assigned by the FAA. This action would provide the FAA with additional data. Using the original Operator Control number would overwrite the original ODR with the additional available data.

The FAA would require that the following additional information be reported: aircraft serial number; station where the discrepancy was detected; FAA-modified Air Transport Association (ATA) Specification 100 code; and aircraft total time and total cycles. A current reporting item, ''type'', has been replaced by manufacturer and model. The addition of these items would increase the effectiveness of operational difficulty reporting and possible tracking of equipment. In addition, the FAA is developing a reporting form, FAA Form No. 8070–2 (see Figure 1), to standardize reporting.

BILLING CODE 4910–13–M

FIGURE 1

U. S. Department of Transportation

Federal Aviation Administration

Operational Difficulty Report

AERONAUTICAL EQUIPMENT

OPERATOR CONTROL NUMBER
ABCD9500337

FAA CONTROL NO.
ATA CODE
7930

MAJOR EQUIPMENT IDENTITY

Enter pertinent data	MANUFACTURER	MODEL	SERIAL NO.	A/C TT	A/C TC
AIRCRAFT	BOEING	757223	91405	2295	3123
POWERPLANT					
PROPELLER					

PROBLEM DESCRIPTION

DATE	STATUS	OPER. DESIG.	OPER. TYPE	REGIS. NUMBER	PREC. PROCED.	NATURE	STAGE OF FLIGHT	STATION	FLIGHT #
10/02/94	C	ABCD	A	N549BR	E	J	CL	OKC	731

Discrepancy/Corrective Action:

On climb #2 engine oil temp indicator pegged on high limit. #2 engine shutdown after 5 minutes at idle thrust. Engine windmilled for 12 minutes before landing.

Removed and replaced #2 oil temp. indicator. Ground ran, ops check normal. MM 79-30-0

SAMPLE

SPECIFIC PART CAUSING PROBLEM

PART NAME	MFG. PART NUMBER	SERIAL#	PART CONDITION	PART/DEFECT LOC.
oil temp. ind.	162BL704G	45678	internal failure	

PART TOTAL TIME	PART TOTAL CYCLES	PART TIME SINCE:	Overhaul / Repair / Inspection
765		765	

COMPONENT NAME	COMPONENT MANUFACTURER	COMPONENT PART#	COMPONENT SERIAL #

COMPONENT TOTAL TIME	COMPONENT TOTAL CYCLES	COMPONENT TIME SINCE:	Overhaul / Repair / Inspection

SUBMITTED BY

NAME	SUB. CODE	DIST. OFF.	ALERT	FILM
ABC Airlines Inc.		S022		

ODR PROTOTYPE 8070-2

BILLING CODE 4910–13–C

Reporting items that pertain to engine or component serial numbers and the time since the last maintenance of a component have been added to the reporting requirements. These items, along with the current requirement to report the emergency procedure effected, would be considered desirable information. The reporting of this information would be beneficial; however, collection of this information should not delay the submission of new reports.

The proposed rule would delete current §§ 121.703(g) and 121.703(h); §§ 127.313(g) and 127.313(h); and §§ 135.415(g) and 135.415(h). Current §§ 121.703(g), 127.313(g), and 135.415(g) contain provisions for air carriers to submit a report even when all of the information required is not available. Current §§ 121.703(h), 127.313(h), and 135.415(h) contain provisions for air carriers to submit supplemental reports when they obtain additional report information. These paragraphs would be deleted because proposed §§ 121.703(e), 127.313(e), and 135.415(e) would require that the following information be included on all reports: manufacturer, model, serial number, and identification number of the aircraft; operator name; date; flight number; station; stage of flight when the failure, malfunction, or defect occurred: the nature of the failure, malfunction, or defect; the FAA-modified ATA code; and the aircraft total time and total cycles. In addition, proposed §§ 121.703(d), 125.409(d), 127.313(d), and 135.415(d) would require that the report be submitted with the 72-hour period. Therefore, the submission of an incomplete report as currently permitted under §§ 121.703(g), 127.313(g), and 135.415(g) would not meet the intent of the proposed rule. Further, the provision for the submission of any additional data as specified in current §§ 121.703(h), 127.313(h), and 135.415(h) would be unnecessary and might add information to SDRS that is not safety related.

Sections 121.703(f), 125.409(f), 127.313(f), and 135.415(f)

Sections 121.703(f), 127.313(f), and 135.415(f) currently state that certificate holders that also hold Type Certificates (TC) (including Supplemental Type Certificates (STC)), Parts Manufacturer Authorization (PMA), or Technical Standard Order (TSO) authorization, or who are licensees of TC, need not report failures, malfunctions, or defects under these sections if the failures are reported under § 21.3 or under part 830 of the NTSB regulations (49 CFR 830). An equivalent § 125.409(f) would be added to provide consistency with parts 121, 127, and 135. In addition, §§ 121.703(f), 127.313(f), and 135.415(f) would be revised by deleting an obsolete reference to § 37.17. Part 37 was removed effective September 9, 1980.

Sections 121.703(g), 125.409(g), 127.313(g), and 135.415(g)

These proposed paragraphs would allow parts 121, 125, 127, and 135 certificate holders to require a certificated domestic or foreign repair station to report a failure, malfunction, or defect discovered by the repair station. Currently, when a repair station finds a failure, malfunction, or defect, this information is reported by both the repair station under § 145.63(a) or § 145.79(c), as appropriate, and the part 121, 125, 127, or 135 certificate holder. Therefore, information about the same problem is reported twice to the FAA. The proposed revision is intended to eliminate these duplicate reports. However, the certificate holder would not be relieved of the responsibility to ensure that these reports are submitted. The proposed rule would require that the part 121, 125, 127, or 135 certificate holder receive a copy of the report submitted by the repair station.

Sections 121.704(a)(1), 125.410(a)(1), 127.314(a)(1), and 135.416(a)(1)

The proposed rule would revise and incorporate the reporting requirements relating to defects in aircraft structures of current §§ 121.703(a)(14) and 121.703(a)(15) into § 121.704(a)(1); of current §§ 127.313(a)(10) and 127.313(a)(11) into § 127.314(a)(1); and of current §§ 135.415(a)(14) and 135.415(a)(15) into § 135.416(a)(1). An equivalent § 125.410(a)(1) also would be added. Proposed §§ 121.704(a)(1), 125.410(a)(1), 127.314(a)(1), and 135.416(a)(1) would contain provisions for reporting information relevant to structural defects of aging aircraft and corrosion protection. The required reporting would focus on discrepancies found in primary structural or principal structural elements relating to corrosion that exceed the manufacturer's Maintenance Manual (MM) allowable limits. As used in this paragraph, the MM includes the aircraft's Structural Repair Manual and other manufacturer's documents, which set forth maintenance requirements.

Sections 121.704(a)(2), 125.410(a)(2), 127.314(a)(2), and 135.416(a)(2)

These proposed sections would revise the reporting requirements for parts 121, 127, and 135, and would add reporting requirements for part 125, for cracks detected only in a primary structure or principal structural element that require the repair or replacement of the structural element. Currently, §§ 121.703(a)(15), 127.313(a)(11), and 135.415(a)(15) require reporting of all cracks in aircraft structures even if the location and size of the crack do not have safety-of-flight implications.

Sections 121.704(a)(3), 125.410(a)(3), 127.314(a)(3), and 135.416(a)(3)

These proposed sections would include a reporting requirement for the detection of disbonding of any primary structure or principal structural element. Currently, air carriers may report disbonding in accordance with § 121.703(c), 127.313(c), or 135.415(c); however, this requirement should be explicit because reporting of disbonding defects is necessary in the early identification of safety-of-flight issues associated with aging aircraft.

Sections 121.704(a)(4), 125.410(a)(4), 127.314(a)(4), and 135.416(a)(4)

These proposed sections would require air carriers to report failures or defects of primary structure or principal structural elements when data developed by a Designated Engineering Representative (DER), under SFAR–36, or other approved repair data that is not found in the manufacturer's MM is used to accomplish the repair.

Some air carriers are uncertain about whether the subsequent detection of the same failure or defect must be reported when the failure or defect was repaired using DER, SFAR–36, or other approved non-MM repair data. The proposed rule would explicitly require that air carriers shall report each and every occurrence of a failure or defect repaired in accordance with DER-approved or other non-MM repair data.

Some Part 135 aircraft may not have Structural Repair Manuals (SRM). Repairs accomplished within the limits of SRM's or MM are not reportable. Repairs developed outside these approved data sources are reportable whether the accepted or approved data is developed by a DER, under SFAR 36, or other approved repair data.

Sections 121.704(a)(5), 125.410(a)(5), 127.314(a)(5), and 135.416(a)(5)

These proposed sections would require the collection of information on any discrepancies found in primary structure or principal structural elements comprised of composite materials. The specific reporting of failures and defects of new and emerging technologies used in the manufacturing of aircraft structures is necessary in the early identification and

resolution of problems that may have an adverse effect on safety.

Sections 121.704(b), 125.410(b), 127.314(b), and 135.416(b)

The proposed sections would require that in addition to the reports required by proposed §§ 121.704(a), 125.410(a), 127.314(a), and 135.416(a), certificate holders would be required to report any other failure or defect that occurs or is detected in an aircraft structure if, in the opinion of the certificate holder, the failure or defect has endangered or may endanger the safe operation of any aircraft.

Sections 121.704(c), 125.410(c), 127.314(c), and 135.416(c)

These proposed sections would require that each report be submitted to a centralized collection point specified by the FAA within the required reporting period. Currently, Service Difficulty Reports are submitted to the FAA FSDO charged with the overall inspection of the certificate holder. However, under the proposal, the certificate holder would be required to make the SDR data available to the FSDO for examination within the time limits specified above in a form and manner acceptable to the Administrator. This would allow PMI's to remain informed of SDR activity, improve the timeliness of FAA processing of the data, and increase the data's availability for analysis. This proposed section also would allow for the use of other means, such as electronic transmission via telephone facsimile or computer modem, to submit reports to the FAA to increase the timeliness of reporting.

Proposed §§ 125.410(c) and 135.416(c) would include provisions for aircraft operating in areas where mail is not collected, thereby preventing mailing within the required 72 hours. In such cases, the reports would be required to be submitted within 72 hours after the aircraft returns to a point where mail is collected.

Sections 121.704(d), 125.410(d), 127.314(d), and 135.416(d)

Under the proposed rule, reports of structural problems would require information on: manufacturer, model, serial number, and registration number of the aircraft; operator name; nature of failure or defect and its location; FAA-modified ATA code; aircraft total time and cycles; and the date and station where the certificate holder found the discrepancy. Optional information would include the identification of the manufacturer's part number or the serial number of the part or component and the time since the last maintenance overhaul, repair, or inspection. To promote standardized reports, the FAA is currently revising a reporting form, FAA Form No. 8070–3 (see Figure 2).

BILLING CODE 4910–13–M

FIGURE 2

U.S. Department of Transportation

Federal Aviation Administration

Structural Difficulty Report

AERONAUTICAL EQUIPMENT

OPERATOR CONTROL NO.
ABCD9500123

FAA CONTROL NO.
ATA CODE
5320

MAJOR EQUIPMENT IDENTITY

ENTER DATA	MANUFACTURER	MODEL	SERIAL NO.	A/C TT	A/C TC
AIRCRAFT	BOEING	737277	92601	27950	26555

WHEN DISCOVERED		
		OPERATIONS
	X	MAINTENANCE

CORROSION LEVEL		
	X	2
		3

PROBLEM DESCRIPTION

DATE	OPER. DESIG.	REGIS. NUMBER	STATION	FLIGHT #
03/13/95	ABCD	N731TA	OKC	812

Discrepancy(Mandatory)Include Length,Width&Depth of Damage/Corrective Action(Optional):

During scheduled inspection, found stringer splice at FS 907, STR 28R corroded beyond limits. Removed and installed new stringer splice per SRM 51 32 2 and SRM 51 10 1.

SAMPLE

SPECIFIC PART CAUSING PROBLEM

MFG. PART NUMBER	SERIAL # (If applicable)	PART NAME:								
6547951			X	Longeron/Stringer		Chord		Doubler		OTHER (specify)
				Bracket/Shear Tie		Web		Rib		
				Frame		Skin		Bulkhead		

PART / DEFECT LOCATION

FUSELAGE STATION (FS)		WATER LINE (WL)		WING STATION (WS)		BUTTOCK LINE (BL)		STRINGER (STR)	
FROM	TO	FROM	TO	FROM	TO	FROM	TO	FROM	TO
907								28R	

OTHER (specify)												
		LH		LH		LH		LH		LH		LH
		RH		RH		RH		RH	X	RH		RH

PART TIME SINCE:			PART CONDITION	CRACK INDUCED BY		
		New	corroded			STRESS
		Rpr./Over.				CORROSION
		Inspection				

SUBMITTED BY

NAME	DIST. OFFICE	ALERT
ABC Airlines Inc.	WP88	

SDR PROTOTYPE 8070-3

BILLING CODE 4910–13–C

Sections 121.704(e), 125.410(e), 127.314(e), and 135.416(e)

These proposed sections would include the current provisions of §§ 121.703(f), 127.313(f), and 135.415(f), which relieve a holder of a Type Certificate, Supplemental Type Certificate, Parts Manufacturer Approval (PMA), a TSO Authorization, or the licensee of a Type Certificate from reporting any failure, malfunction, or defect under this section if reports are submitted on the same failure, malfunction, or defect under § 21.3 or under the accident reporting provisions of Part 830 of the NTSB regulations. Proposed § 125.410(e) would include a similar provision.

Sections 121.704(f), 125.410(f), 127.314(f), and 135.416(f)

These proposed sections would allow parts 121, 125, 127, and 135 certificate holders to delegate to a certificated repair station the task of reporting the detection of a failure, malfunction, or defect discovered by the repair station. Currently, when a repair station finds a failure, malfunction, or defect, this information is reported by both the repair station under § 145.63(a) or § 145.79(c), as appropriate, and the part 121, 125, 127, or 135 certificate holder. This proposed section would eliminate duplicate reporting of the same failures or defects but would not relieve the certificate holder of the responsibility for ensuring that the report is submitted to the FAA. In addition, the proposed rule would require that the certificate holder receive a copy of the report submitted by the repair station.

Sections 121.705, 127.315, and 135.417

Under the proposal, §§ 121.705(a), 127.315(a), and 135.417(a) would remain in effect, requiring that operators report to the Administrator interruptions to flights, unscheduled changes of aircraft en route, or unscheduled stops or diversions from routes, caused by known or suspected mechanical difficulties or malfunctions that are not required to be reported under proposed §§ 121.703 and 121.704, 127.313 and 127.314, and 135.415 and 135.416, respectively. The requirements of current §§ 121.705 (b) and (c), 127.315(b), and 135.417(b) would be deleted because this is reliability data and does not have safety-of-flight implications. In addition, these items currently are required to be monitored under § 121.373, 127.136, and 135.431.

Sections 125.409(b) and 127.313(b)

Under the proposal, § 127.313(b) would be corrected to state that, for the purposes of this section, during flight means the period from the moment the helicopter leaves the surface of the earth *on* (rather than ''or'') takeoff until it touches down on landing. An equivalent paragraph would also be added to § 125.409(b).

Section 127.313(a)(8)

The proposed rule would redesignate current § 127.313(a)(13) as § 127.313(a)(8). This paragraph concerns main rotor and auxiliary rotor systems.

Sections 145.63 and 145.79

The proposed rule would revise §§ 145.63 and 145.79 to allow certificated domestic and foreign repair stations, respectively, to be delegated by a part 121, 125, 127, or 135 certificate holder to submit operational and structural difficulty reports to the FAA on behalf of the certificate holder. A repair station would submit these reports, as delegated, when it discovers a defect or unairworthy condition of an aircraft, powerplant, propeller, or any component thereof. When a certificated repair station submits a report for a part 121, 125, 127, or 135 certificate holder, the repair station would not be required to submit a separate report under § 145.63(a) or 145.79(c), as appropriate.

Currently, when a certificated repair station finds a defect or unairworthy condition, the repair station and the part 121, 125, 127, or 135 certificate holder report the condition or defect to the FAA. The proposed rule would require that only one report be submitted in such circumstances.

Paperwork Reduction Act Approval

The reporting burden associated with parts 121, 125, 127, 135, and 145 of the Federal Aviation Regulations has been approved by OMB under control numbers 2120–003, 2120–008, 2120–0010, 2120–0039, and 2120–0085.

This NPRM proposes to clarify the reporting burden. The clarification may cause a reduction in burden, because it may lead to a reduction in redundancy of reporting. Some 125 certificate holders may have a slight reduction in reporting. There are minimal additional reporting requirements associated with this proposed rule.

Regulatory Evaluation Summary

Executive Order 12866 established the requirement that, within the extent permitted by law, a Federal regulatory action may be undertaken only if the potential benefits to society for the regulation outweigh the potential costs to society. In response to this requirement, and in accordance with Department of Transportation (DOT) policies and procedures, the FAA has estimated the anticipated benefits and costs of this rulemaking action. The FAA has determined that this proposed rule is not a ''significant rulemaking action,'' as defined by Executive Order 12866 (Regulatory Planning and Review), and is not considered significant under DOT Order 2100.5, Policies and Procedures for Simplification, Analysis, and Review of Regulations. The anticipated costs and benefits associated with this proposed rule are stated below.

The total number of reports submitted to the FAA is not expected to change substantially. Although more specific and detailed reports will generally be required, the clarification of reporting requirements should expedite the reporting process. Therefore, the costs of complying with the proposed rule change are not expected to differ significantly from the costs of complying with the present requirements. Increases in the volume of some types of reports are expected to be offset by decreases in the volume of other types of reports. New requirements to report on-ground incidents that may have implications for flight safety and those pertaining to aging aircraft issues should increase the volume of reports. Other provisions, however, such as the elimination of duplicate reporting by the air carriers and repair stations and the elimination of reports involving issues of reliability (e.g., unscheduled stops or diversions from routes), would reduce the number of required reports. In addition, Part 125 operators would not be required to report as many incidents as is currently required. The FAA believes that the increased and decreased reporting requirements are offsetting but invites comments from the public regarding the validity of this assumption.

The purpose of the proposed rule is to enhance air carrier safety by clarifying and standardizing reporting requirements and facilitating the timely flow of information to the FAA. These data identify mechanical problems that may be a serious hazard to the operation of an aircraft. The information collected would be used to develop corrective actions to eliminate the identified problems. Increased standardization of these reports should make it easier for FAA personnel to interpret their significance, thereby reducing the number of manhours devoted by the FAA to processing and interpreting the information gleaned from these reports.

One major safety benefit would result from the clarification of reporting requirements that specifically address structural defects normally associated with aging aircraft. Another benefit

would derive from the new requirement that air carriers report problems that occur during ground operations that could affect flight safety.

The proposed rule would also explicitly permit the submission of the required reports in an electronic form. Electronic submission of data will give the FAA more timely information, thereby permitting earlier recognition of significant trends. In addition, the allowance of electronic reporting should reduce the processing and storage costs of the air carriers. The costs of duplicating these reports, mailing them to the FAA, and record-keeping should all be reduced. Because of the negligible nature of many of these processing costs, however, any cost-savings should be quite minor. In addition, the need for FAA-compatible equipment/software may dilute some of these cost-savings, at least initially. The FAA invites comments from the industry regarding the potential magnitude of these cost-savings.

Regulatory Flexibility Determinations

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to ensure that small entities are not unnecessarily and disproportionately burdened by government regulations. The RFA requires agencies to review rules that may have a ''significant economic impact on a substantial number of small entities.''

Under FAA Order 2100.14A, the criterion for a ''substantial impact'' is a number that is not less than 11 and that is more than one third of the small entities subject to the rule. For operators of aircraft for hire, a small operator is one that owns, but not necessarily operates, nine or fewer aircraft. The FAA's criterion for a ''significant impact'' is $116,300 or more per year for a scheduled operator whose entire fleet has a seating capacity of 60 seats or more, $65,000 for a scheduled operator with a fleet including smaller aircraft, and $4,600 or more for an unscheduled operator.

Any incremental costs or cost-savings per operator are likely to be nominal, however, for reasons previously noted. The FAA has therefore determined that the proposed rule would not have a significant impact on a substantial number of small entities. The FAA solicits comments from the affected segment of the aviation industry regarding the possible extent of any cost impacts.

International Trade Impact Assessment

The incremental costs and cost savings associated with the proposed rule changes are not significant enough to result in relative trade advantages to either U.S. or foreign entities. Therefore, the FAA has determined that they would have no impact on the sale of foreign products domestically, or the sale of U.S. products in foreign markets.

Federalism Implications

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

Conclusion

For the reasons discussed in the preamble, and based on the findings in the Regulatory Flexibility Determination and International Trade Impact Analysis, the FAA has determined that this proposed regulation is not a significant regulatory action under Executive Order 12866. In addition, the FAA certifies that this proposal, if adopted, 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. This proposal is not considered significant under DOT Order 2100.5, Policies and Procedures for Simplification, Analysis, and Review of Regulations. The FAA has determined that a separate regulatory evaluation is not needed for this proposal, and all information related to the costs and benefits, including an initial Regulatory Flexibility Determination and an International Trade Impact Analysis, is included in this document under the heading ''Regulatory Evaluation Summary.''

List of Subjects

14 CFR Part 121

Air carriers, Aircraft, Aviation safety, Reporting and recordkeeping requirements, Safety, Transportation.

14 CFR Part 125

Aircraft, Aviation safety, Reporting and recordkeeping requirements, Safety.

14 CFR Part 127

Air carriers, Aircraft, Aviation safety, Helicopters, Reporting and recordkeeping requirements.

14 CFR Part 135

Air taxis, Aircraft, Aviation safety, Reporting and recordkeeping requirements.

14 CFR Part 145

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR parts 121, 125, 127, 135, and 145 of the Federal Aviation Regulations as follows:

PART 121—CERTIFICATION AND OPERATIONS: DOMESTIC, FLAG, AND SUPPLEMENTAL AIR CARRIERS AND COMMERCIAL OPERATORS OF LARGE AIRCRAFT

1. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. app. 1354(a), 1355, 1356, 1357, 1401, 1421–1430, 1472, 1485, and 1502; 49 U.S.C. 106(g).

2. Section 121.703 is amended by revising the heading and paragraphs (a), (c), (d), (e), (f), and (g) and by removing paragraph (h) to read as follows:

§ 121.703 Operational difficulty reports.

(a) Each certificate holder shall report the occurrence or detection of each failure, malfunction, or defect concerning—

(1) Any fire and, when monitored by a related fire-warning system, whether the fire-warning system functioned properly;

(2) Any false fire or smoke warnings that require the use of emergency procedures;

(3) An engine exhaust system that causes damage to the engine, adjacent structure, equipment, or components;

(4) An aircraft component that causes the accumulation or circulation of smoke, vapor, or toxic or noxious fumes requiring the use of emergency procedures;

(5) Any engine flameout or shutdown during ground or flight operations, excluding intentional engine shutdowns during such operations (e.g., flight crew training, test flights, or while taxiing to reduce fuel consumption);

(6) A propeller feathering system or ability of the system to control overspeed;

(7) A fuel or fuel-dumping system that affects fuel flow or causes hazardous leakage during flight;

(8) A landing gear extension or retraction or the opening or closing of landing gear doors during flight;

(9) Any brake system component that results in any detectable loss of brake actuating force when the aircraft is in motion on the ground, excluding failures, malfunctions, or defects that are deferrable according to the

Minimum Equipment List as provided for in § 91.213;

(10) Any aircraft component or system that results in aborted takeoffs after initiation of the takeoff roll or the taking of emergency actions during flight; and

(11) Any emergency evacuation system or component including any exit door, passenger emergency evacuation lighting system, or evacuation equipment that is found to be defective, or that fails to perform the intended function during an actual emergency or during training, testing, maintenance, demonstrations, or inadvertent deployments, excluding failures, malfunctions, or defects that are deferrable according to the Minimum Equipment List as provided for in § 91.213.

(b) * * *

(c) In addition to the reports required by paragraph (a) of this section, each certificate holder shall report any other failure, malfunction, or defect in an aircraft, system, component, or powerplant that occurs or is detected at any time if, in its opinion, that failure, malfunction, or defect has endangered or may endanger the safe operation of an aircraft.

(d) Each certificate holder shall submit each report required by this section, covering each 24-hour period beginning at 0900 local time of each day and ending at 0900 local time on the next day, to a centralized collection point as specified by the FAA. Each certificate holder also shall make the report data available for examination by the Flight Standards District Office charged with the overall inspection of the certificate holder in a form and manner acceptable to the Administrator. Each report of occurrences during a 24-hour period shall be submitted to the FAA within the next 72 hours. However, a report that is due on Saturday or Sunday may be submitted on the following Monday, and one that is due on a holiday may be submitted on the next work day.

(e) The certificate holder shall submit the reports required by this section in an electronic form or another form acceptable to the Administrator. The reports shall include the information listed in paragraphs (e)(1) through (e)(6) of this section and should include as much information that is available for paragraphs (e)(7) through (e)(9) of this section:

(1) Manufacturer, model, serial number, and registration number of the aircraft.

(2) The name of the operator.

(3) The date; flight number; station where the failure, malfunction, or defect was detected; and the stage during which the failure, malfunction, or defect occurred (e.g., preflight, taxi, takeoff, climb, cruise, descent, approach, landing, or inspection).

(4) The nature of the failure, malfunction, or defect.

(5) The applicable FAA modified Air Transport Association Specification 100 code (ATA code).

(6) The aircraft total time and total cycles.

(7) The engine or component serial number.

(8) The emergency procedure effected.

(9) Identification of the part and system involved, including available information pertaining to type designation of the major component and the time since the last maintenance overhaul, repair, or inspection.

(f) A certificate holder that is also the holder of a Type Certificate (including a Supplemental Type Certificate), a Parts Manufacturer Approval (PMA), or a Technical Standard Order (TSO) authorization, or that is a licensee of a Type Certificate, need not report a failure, malfunction, or defect under this section if the certificate holder has reported the failure, malfunction, or defect under § 21.3 of this chapter or under the accident reporting provisions of part 830 of the regulations of the National Transportation Safety Board.

(g) A report required by this section may be submitted by a certificated repair station when the reporting task has been assigned to it by a part 121 certificate holder. However, the part 121 certificate holder remains primarily responsible for ensuring compliance with the provisions of this section. The part 121 certificate holder shall receive a copy of each report submitted by the repair station.

3. Section 121.704 is added to read as follows:

§ 121.704 Structural difficulty reports.

(a) Each certificate holder shall report the occurrence or detection of each failure or defect of each primary structure or principal structural element, as defined in the manufacturer's Maintenance Manual, which includes the aircraft's Structural Repair Manual, related to—

(1) Corrosion that requires rework or blendout that exceeds the manufacturer's Maintenance Manual (MM) allowable limits and requires a repair or a complete or partial replacement of a primary structure or principal structural element;

(2) Cracks that require a repair or a complete or partial replacement of a primary structure or principal structural element;

(3) Disbonding that requires a repair or a complete or partial replacement of a primary structure or principal structural element;

(4) Failures or defects repaired in accordance with data approved by a Designated Engineering Representative (DER) or other approved data not contained in the manufacturer's MM; and

(5) Any crack, fracture, or delamination of a primary structure or principal structural element composed of composite materials.

(b) In addition to the reports required by paragraph (a) of this section, each certificate holder shall report any other failure or defect in aircraft structure that occurs or is detected at any time if, in its opinion, that failure or defect has endangered or may endanger the safe operation of any aircraft.

(c) Each certificate holder shall submit each report required by this section covering such 24-hour period beginning at 0900 local time of each day and ending at 0900 local time on the next day, to a centralized collection point as specified by the FAA. Each certificate holder also shall make the report data available for examination by the Flight Standards District Office charged with the overall inspection of the certificate holder in a form and manner acceptable to the Administrator. Each report of occurrences during a 24-hour period shall be submitted to the FAA within the next 72 hours. However, a report that is due on Saturday or Sunday may be submitted on the following Monday, and one that is due on a holiday may be submitted on the next work day.

(d) The certificate holder shall submit the reports required by this section in an electronic form or another form acceptable to the Administrator. The reports shall include the following information listed in paragraphs (d)(1) through (d)(6) of this section and should include as much information that is available for paragraph (d)(7) of this section:

(1) Manufacturer, model, serial number, and registration number of the aircraft.

(2) The name of the operator.

(3) The nature of the failure or defect and its location.

(4) The FAA-modified Air Transport Association Specification 100 code (ATA code).

(5) The aircraft total time and cycles.

(6) The date and station where the failure or defect was discovered.

(7) Identification of the part or component involved (e.g., manufacturer's part number and serial number) and the time since the last maintenance overhaul, repair, or inspection.

(e) A certificate holder that is also the holder of a Type Certificate (including a Supplemental Type Certificate), a Parts Manufacturer Approval (PMA), or a TSO authorization, or that is a licensee of a Type Certificate, need not report a failure, malfunction, or defect under this section if the certificate holder has reported the failure, malfunction, or defect under § 21.3 of this chapter or under the accident reporting provisions of part 830 of the regulations of the National Transportation Safety Board.

(f) The reports required by this section may be submitted by a certificated repair station when the reporting task has been assigned to it by the part 121 certificate holder. However, the responsibility for ensuring compliance with the provisions of this section may not be delegated by the part 121 certificate holder. The part 121 certificate holder shall receive a copy of each report.

4. Section 121.705 is revised to read as follows:

§ 121.705 Mechanical interruption summary report.

Each certificate holder shall regularly and promptly submit a summary report to the Administrator following each interruption to a flight, unscheduled change of aircraft en route, or unscheduled stop or diversion from a route, caused by known or suspected mechanical difficulties or malfunctions that are not required to be reported under §§ 121.703 or 121.704.

PART 125—CERTIFICATION AND OPERATIONS: AIRPLANES HAVING A SEATING CAPACITY OF 20 OR MORE PASSENGERS OR A MAXIMUM PAYLOAD CAPACITY OF 6,000 POUNDS OR MORE

5. The authority citation for part 125 is revised to read as follows:

Authority: 49 U.S.C. app. 1354, 1421 through 1430, and 1502; 49 U.S.C. 106(g).

6. Section 125.409 is revised to read as follows:

§ 125.409 Operational difficulty reports.

(a) Each certificate holder must report the occurrence or detection of each failure, malfunction, or defect in an aircraft concerning—

(1) Any fire and, when monitored by a related fire-warning system, whether the fire-warning system functioned properly;

(2) Any false fire or smoke warnings that require the use of emergency procedures;

(3) An engine exhaust system that causes damage to an engine, adjacent structure, equipment, or components;

(4) An aircraft component that causes the accumulation or circulation of smoke, vapor, or toxic or noxious fumes requiring the use of emergency procedures;

(5) Any engine flameout or shutdown during ground or flight operations, excluding intentional engine shutdowns during such operations (e.g., flight crew training, test flights, or taxiing to reduce fuel consumption);

(6) A propeller feathering system or ability of the system to control overspeed;

(7) A fuel or fuel dumping system that affects fuel flow or causes hazardous leakage during flight;

(8) A landing gear extension or retraction or the opening or closing of landing gear doors during flight;

(9) Any brake system component that results in any detectable loss of brake actuating force when the aircraft is in motion on the ground, excluding failures, malfunctions, or defects that are deferrable according to the Minimum Equipment List as provided for in § 91.213;

(10) Any aircraft component or system that results in aborted takeoffs after initiation of the takeoff roll or the taking of emergency actions during flight; and

(11) Any emergency evacuation system or component including any exit door, passenger emergency evacuation lighting system, or evacuation equipment that is found to be defective, or that fails to perform the intended function during an actual emergency or during training, testing, maintenance, demonstrations, or inadvertent deployments, excluding failures, malfunctions, or defects that are deferrable according to the Minimum Equipment List as provided for in § 91.213.

(b) For the purposes of this section, during flight means the period from the moment the aircraft leaves the surface of the earth on takeoff until it touches down on landing.

(c) In addition to the reports required by paragraph (a) of this section, each certificate holder must report any other failure, malfunction, or defect in an aircraft, system, component, or powerplant that occurs or is detected at any time if, in its opinion, that failure, malfunction, or defect has endangered or may endanger the safe operation of an aircraft it uses.

(d) Each certificate holder must submit each report required by this section as prescribed in paragraphs (a) and (c) of this section, covering each 24-hour period beginning at 0900 local time of each day and ending at 0900 local time on the next day, to the location where the data base is maintained. Each certificate holder also must make the report data available for examination by the Flight Standards District Office charged with the overall inspection of the certificate holder in a form and manner acceptable to the Administrator. Each report of occurrences during a 24-hour period shall be submitted to the FAA within the next 72 hours. However, a report that is due on Saturday or Sunday may be submitted on the following Monday, and one that is due on a holiday may be submitted on the next work day. For aircraft operating in areas where mail is not collected, reports may be submitted within 24 hours after the aircraft returns to a point where mail is collected.

(e) The certificate holder shall submit the reports required by this section in an electronic form or another form acceptable to the Administrator. The reports shall include the information listed in paragraphs (e)(1) to (e)(6) of this section and should include as much information that is reasonably available for paragraphs (e)(7) to (e)(9) of this section:

(1) Manufacturer, model serial number, and registration number of the aircraft.

(2) The name of the operator.

(3) The date; flight number; station where the failure, malfunction, or defect was detected; and the stage during which the failure, malfunction, or defect occurred (e.g., preflight, taxi, takeoff, climb, cruise, descent, approach, landing, or inspection).

(4) The nature of the failure, malfunction, or defect.

(5) The applicable FAA-modified Air Transport Association Specification 100 code (ATA code).

(6) The aircraft total time and total cycles.

(7) The engine or component serial number.

(8) The emergency procedure effected (e.g., unscheduled landing and emergency descent).

(9) Identification of the part and system involved, including available information pertaining to type designation of the major component and the time since the last maintenance overhaul, repair, or inspection.

(f) A certificate holder that is also the holder of a Type Certificate (including a Supplemental Type Certificate), a Parts Manufacturer Approval (PMA), or a Technical Standard Order (TSO) authorization or that is a licensee of a Type Certificate need not report a failure, malfunction, or defect under this section if it has reported the failure, malfunction, or defect under § 21.3 of this chapter or under the accident reporting provisions of part 830 of the

regulations of the National Transportation Safety Board.

(g) Reports prescribed in paragraph (e) of this section may be submitted by a certificated repair station when the reporting task has been delegated by a part 125 certificate holder, under the provisions of §§ 145.63(d)(2) or 145.79(e)(2) of this chapter. However, the responsibility for ensuring compliance with the provisions of this section may not be delegated by the part 125 certificate holder. The part 125 certificate holder must receive a copy of each report.

7. Section 125.410 is added to read as follows:

§ 125.410 Structural difficulty reports.

(a) Each certificate holder shall report the occurrence or detection of each failure or defect of each primary structure or principal structural element, as defined in the manufacturer's Maintenance Manual (which includes the aircraft's Structural Repair Manual and other manufacturer's documents that set forth maintenance requirements) related to—

(1) Corrosion that requires rework or blendout that exceeds the manufacturer's Maintenance Manual (MM) allowable limits and requires a repair or a complete or partial replacement of a primary structure or principal structural element;

(2) Cracks that require a repair or a complete or partial replacement of a primary structure or principal structural element;

(3) Disbonding that requires a repair or a complete or partial replacement of a primary structure or principal structural element;

(4) Failures or defects repaired in accordance with Designated Engineering Representative (DER) data or other approved data not contained in the manufacturer's MM; and

(5) Any crack, fracture, or delamination of a primary structure or principal structural element composed of composite materials.

(b) In addition to the reports required by paragraph (a) of this section, each certificate holder shall report any other failure or defect in aircraft structure that occurs or is detected at any time if, in its opinion, that failure or defect has endangered or may endanger the safe operation of any aircraft it uses.

(c) Each certificate holder shall submit each report required by this section, as prescribed in paragraphs (a) and (b) of this section, covering each 24-hour period beginning at 0900 local time of each day and ending at 0900 local time on the next day, to a centralized collection point as specified by the FAA. Each certificate holder also shall make the report data available for examination by the Flight Standards District Office charged with the overall inspection of the certificate holder in a form and manner acceptable to the Administrator. Each report of occurrences during a 24-hour period shall be submitted to the FAA within the next 72 hours. However, a report that is due on Saturday or Sunday may be submitted on the following Monday, and one that is due on a holiday may be submitted on the next work day. For aircraft operating in areas where mail is not collected, reports may be submitted within 24 hours after the aircraft returns to a point where the mail is collected.

(d) The certificate holder shall submit the reports required by this section in an electronic form or another form acceptable to the Administrator. The reports must include the following information listed in paragraph (d)(1) through (d)(6) of this section and should include as much information that is reasonably available for paragraph (d)(7) of this section:

(1) Manufacturer, model, serial number, and registration number of the aircraft.

(2) The name of the operator.

(3) The nature of the failure or defect and its location.

(4) The FAA-modified Air Transport Association Specification 100 code (ATA code).

(5) The aircraft total time and cycles.

(6) The data and station where the failure or defect was discovered.

(7) Identification of the part or component involved (e.g., manufacturer's part number and serial number) and the time since the last maintenance overhaul, repair, or inspection.

(e) A certificate holder that is also the holder of a Type Certificate (including a Supplemental Type Certificate), a Parts Manufacturer Approval (PMA), or a Technical Standard Order (TSO) authorization or that is a licensee of a Type Certificate need not report a failure, malfunction, or defect under this section if it has reported the failure, malfunction, or defect under § 21.3 of this chapter or under the accident reporting provisions of part 830 of the regulations of the National Transportation Safety Board.

(f) Reports prescribed in paragraph (d) of this section may be submitted by a certificated repair station when the reporting task has been assigned by the part 125 certificate holder under the provisions of §§ 145.63(d)(2) or 145.79(e)(2) of this chapter. However, the responsibility for ensuring compliance with the provisions of this section may not be delegated by the part 125 certificate holder. The part 125 certificate holder shall receive a copy of each report.

PART 127—CERTIFICATION AND OPERATIONS OF SCHEDULED AIR CARRIERS WITH HELICOPTERS

8. The authority citation for part 127 continues to read as folllows:

Authority: 49 U.S.C. app. 1354(a) 1421, 1422, 1423, 1424, 1425, 1430; 49 U.S.C. 106(g).

9. Section 127.313 is revised to read as follows:

§ 127.313 Operational difficulty reports.

(a) Each air carrier shall report the occurrences or detection of each failure, malfunction, or defect concerning—

(1) Any fire and, when monitored by a related fire-warning system, whether the fire-warning system functioned properly;

(2) Any false fire or smoke warnings that require the use of emergency procedures;

(3) An engine exhaust system that causes damage to an engine, adjacent structure, equipment, or components;

(4) A helicopter component that causes the accumulation or circulation of smoke, vapor, or toxic or noxious fumes requiring the use of emergency procedures;

(5) Any engine flameout or shutdown during ground or flight operations, excluding intentional engine shutdowns during such operations (e.g., flight crew training, test flights, or taxiing to reduce fuel consumption);

(6) A fuel or fuel dumping system that affects fuel flow or causes hazardous leakage during flight;

(7) Any helicopter component or system that results in aborted takeoffs after initiation of the takeoff or the taking of emergency actions during flight;

(8) Main rotor or auxiliary rotor system; and

(9) Any emergency evacuation system or component including any exit door, passenger emergency evacuation lighting system, or evacuation equipment that is found to be defective, or that fails to perform the intended function during an actual emergency or during training, testing, maintenance, demonstrations, or inadvertent deployments, excluding failures, malfunctions, or defects that are deferrable according to the Minimum Equipment List as provided for in § 91.213.

(10) A landing gear extension or retraction, or the opening or closing of landing gear doors during flight;

(11) Any brake system component that results in any detectable loss of brake actuating force when the aircraft is in motion on the ground.

(b) For the purposes of this section during flight means the period from the moment the helicopter leaves the surface of the earth on takeoff until it touches down on landing.

(c) In addition to the reports required by paragraph (a) of this section, each air carrier shall report any other failure, malfunction, or defect in a helicopter, system, component, or powerplant that occurs or is detected at any time if, in the air carrier's opinion, the failure, malfunction, or defect has endangered or may endanger the safe operation of the helicopter it uses.

(d) Each air carrier shall submit each report required by this section as prescribed in paragraphs (a) and (c) of this section, covering each 24-hour period beginning at 0900 local time of each day and ending at 0900 local time on the next day, to a centralized collection point as specified by the FAA. Each certificate holder also shall make the report data available for examination by the Flight Standards District Office charged with the overall inspection of the certificate holder in a form and manner acceptable to the Administrator. Each report of occurrences during a 24-hour period shall be submitted to the FAA within the next 72 hours. However, a report that is due on Saturday or Sunday may be submitted on the following Monday, and one that is due on a holiday may be submitted on the next work day.

(e) The air carrier shall submit the reports required by this section is an electronic form or another form acceptable to the Administrator. The reports shall include the information listed in paragraphs (e)(1) through (e)(6) of this section and should include as much information that is reasonably available for paragraphs (e)(7) through (e)(9) of this section:

(1) Manufacturer, model, serial number, and registration number of the helicopter.

(2) The name of the air carrier.

(3) The date; flight number; station where the failure, malfunction, or defect was detected; and the stage during which the failure, malfunction, or defect occurred (e.g., preflight, taxi, takeoff, climb, cruise, descent, landing, or inspection).

(4) The nature of the failure, malfunction, or defect.

(5) The applicable FAA-modified Air Transport Association Specification 100 code (ATA code).

(6) The helicopter total time and total cycles.

(7) The engine or component serial number.

(8) The emergency procedure affected (e.g., unscheduled landing and emergency descent).

(9) Identification of the part and system involved, including available information pertaining to type designation of the major component and the time since the last maintenance overhaul, repair, or inspection.

(f) A certificate holder that is also the holder of a Type Certificate (including a Supplemental Type Certificate), a Parts Manufacturer Approval (PMA), or a Technical Standard Order (TSO) authorization, or that is a licensee of a Type Certificate, need not report a failure, malfunction, or defect under this section if it has reported the failure, malfunction, or defect under § 21.3 of this chapter or under the accident reporting provisions of part 830 of the regulations of the National Transportation Safety Board.

(g) Reports prescribed in paragraph (e) of this section may be submitted by a certificated repair station when the reporting task has been assigned by a part 127 air carrier, under the provisions of §§ 145.63(d)(3) or 145.79(e)(3) of this chapter. However, the responsibility for ensuring compliance with the provisions of this section may not be delegated by the part 127 air carrier. The part 127 air carrier shall receive a copy of each report.

10. Section 127.314 is added to read as follows:

§ 127.314 Structural difficulty reports.

(a) Each air carrier shall report the occurrence or detection of each failure or defect of each primary structure or principal structural element as defined in the manufacturer's Maintenance Manual (which includes the aircraft's Structural Repair Manual and other manufacturer's documents that set forth maintenance requirements) related to—

(1) Corrosion that requires rework or blendout that exceeds the manufacturer's Maintenance Manual (MM) allowable limits and requires a repair or a complete or partial replacement of a primary structure or principal structural element;

(2) Cracks that require a repair or a complete or partial replacement of a primary structure or principal structural element;

(3) Disbonding that requires a repair or a complete or partial replacement of a primary structure or principal structural element;

(4) Failures or defects repaired in accordance with Designated Engineering Representative (DER) data or other approved data not contained in the manufacturer's MM; and

(5) Any crack, fracture, or delamination of a primary structure or principal structural element composed of composite materials.

(b) In addition to the reports required by paragraph (a) of this section, each air carrier shall report any other failure or defect in helicopter structure that occurs or is detected at any time if, in its opinion, that failure or defect has endangered or may endanger the safe operation of any helicopter it uses.

(c) Each air carrier shall submit each report required by this section, as prescribed in paragraphs (a) and (b) of this section, covering each 24-hour period beginning at 0900 local time of each day and ending at 0900 local time on the next day, to the location where the data base is maintained. Each certificate holder also shall make the report data available for examination by the Flight Standards District Office charged with the overall inspection of the certificate holder in a form and manner acceptable to the Administrator. Each report of occurrences during a 24-hour period shall be submitted to the FAA within the next 72 hours. However, a report that is due on Saturday or Sunday may be submitted on the following Monday, and one that is due on a holiday may be submitted on the next work day.

(d) The air carrier shall submit the reports required by this section in an electronic form or another form acceptable to the Administrator. The reports shall include the information listed in paragraphs (d)(1) through (d)(6) of this section and should include as much information that is reasonably available for paragraph (d)(7) of this section:

(1) Manufacturer, model, serial number, and registration number of the helicopter.

(2) The name of the operator.

(3) The nature of the failure or defect and its location.

(4) The FAA-modified Air Transport Association Specification 100 code (ATA code).

(5) The helicopter total time and cycles.

(6) The date and station where the failure or defect was discovered.

(7) Identification of the part or component involved (e.g., manufacturer's part number and serial number) and the time since the last maintenance overhaul, repair, or inspection.

(e) An air carrier that is also the holder of a Type Certificate (including a Supplemental Type Certificate), a Parts Manufacturer Approval (PMA), or

a Technical Standard Order (TSO) authorization or that is a licensee of a Type Certificate need not report a failure, malfunction, or defect under this section if it has reported the failure, malfunction, or defect under § 21.3 of this chapter or under the accident reporting provisions of part 830 of the regulations of the National Transportation Safety Board.

(f) Reports prescribed in paragraph (d) of this section may be submitted by a certificated repair station when the reporting task has been assigned by the part 127 air carrier under the provisions of §§ 145.63(d)(3) or 145.79(e)(3) of this chapter. However, the responsibility for ensuring compliance with the provisions of this section may not be delegated by the part 127 air carrier. The part 127 air carrier shall receive a copy of each report.

11. Section 127.315 is revised to read as follows:

§ 127.315 Mechanical interruption summary report.

Each certificate holder shall regularly and promptly submit a summary report to the Administrator following each interruption to a flight, unscheduled change of aircraft en route, or unscheduled stop or diversion from a route, caused by known or suspected mechanical difficulties or malfunctions that are not required to be reported under § 127.313 or § 127.314.

12. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. app. 1354(a), 1355(a), 1421 through 1431, and 1502; 49 U.S.C. 106(g).

13. Section 135.415 is amended by revising the heading and paragraphs (a), (c), (d), (e), (f), and (g) and by removing paragraphs (a)(12) through (a)(16) and paragraph (h) to read as follows:

§ 135.415 Operational difficulty reports.

(a) Each certificate holder shall report the occurrence or detection of each failure, malfunction, or defect in an aircraft concerning—

(1) Any fire and, when monitored by a related fire-warning system, whether the fire-warning system functioned properly;

(2) Any false fire or smoke warnings that require the use of emergency procedures;

(3) An engine exhaust system that causes damage to an engine, adjacent structure, equipment or components;

(4) An aircraft component that causes the accumulation or circulation of smoke, vapor, or toxic or noxious fumes requiring the use of emergency procedures;

(5) Any engine flameout or shutdown during ground or flight operations, excluding intentional engine shutdowns during such operations (e.g., flight crew training, test flights, or taxiing to reduce fuel consumption);

(6) A propeller feathering system or ability of the system to control overspeed;

(7) A fuel or fuel-dumping system that affects fuel flow or causes hazardous leakage during flight;

(8) A landing gear extension or retraction or the opening or closing of landing gear doors during flight;

(9) Any brake system component that results in any detectable loss of brake actuating force when the aircraft is in motion on the ground, excluding failures, malfunctions, or defects that are deferrable according to the Minimum Equipment List as provided for in § 91.213;

(10) Any aircraft component or system that results in aborted takeoffs after initiation of the takeoff roll or the taking of emergency actions during flight; and

(11) Any emergency evacuation system or component including any exit door, passenger emergency evacuation lighting system, or evacuation equipment that is found to be defective, or that fails to perform the intended function during an actual emergency or during training, testing, maintenance, demonstrations, or inadvertent deployments, excluding failures, malfunctions, or defects that are deferrable according to the Minimum Equipment List as provided for in § 91.213.

(b) * * *

(c) In addition to the reports required by paragraph (a) of this section, each certificate holder shall report any other failure, malfunction, or defect in an aircraft, system, component, or powerplant that occurs or is detected at any time if, in its opinion, that failure, malfunction, or defect has endangered or may endanger the safe operation of an aircraft it uses.

(d) Each certificate holder shall submit each report required by this section as prescribed in paragraphs (a) and (c) of this section, covering each 24-hour period beginning at 0900 local time of each day and ending at 0900 local time on the next day, to the location where the data base is maintained. Each certificate holder also shall make the report data available for examination by the Flight Standards District Office charged with the overall inspection of the certificate holder in a form and manner acceptable to the Administrator. Each report of occurrences during a 24-hour period shall be submitted to the FAA within the next 72 hours. However, a report that is due on Saturday or Sunday may be submitted on the following Monday, and one that is due on a holiday may be submitted on the next work day. For aircraft operating in areas where mail is not collected, reports may be submitted within 24 hours after the aircraft returns to a point where mail is collected.

(e) The certificate holder shall submit the reports required by this section in an electronic form or another form acceptable to the Administrator. The reports must include the information listed in paragraphs (e)(1) through (e)(6) of this section and should include as much information that is reasonably available for paragraphs (e)(7) to (e)(9) of this section:

(1) Manufacturer, model, serial number, and registration number of the aircraft.

(2) The name of the operator.

(3) The date; flight number; station where the failure, malfunction, or defect was detected; and the stage during which the failure, malfunction, or defect occurred (e.g., preflight, taxi, takeoff, climb, cruise, descent, approach, landing, or inspection).

(4) The nature of the failure, malfunction, or defect.

(5) The applicable FAA-modified Air Transport Association Specification 100 code (ATA code).

(6) The aircraft total time and total cycles.

(7) The engine or component serial number.

(8) The emergency procedure affected (e.g., unscheduled landing and emergency descent).

(9) Identification of the part and system involved, including available information pertaining to type designation of the major component and the time since the last maintenance overhaul, repair, or inspection.

(f) A certificate holder that is also the holder of a Type Certificate (including a Supplemental Type Certificate), a Parts Manufacturer Approval (PMA), or a Technical Standard Order (TSO) authorization or that is a licensee of a Type Certificate need not report a failure, malfunction, or defect under this section if it has reported the failure, malfunction, or defect under § 21.3 of this chapter or under the accident reporting provisions of part 830 of the regulations of the National Transportation Safety Board.

(g) Reports prescribed in paragraph (e) of this section may be submitted by a certificated repair station when the reporting task has been assigned by a part 135 certificate holder, under the provisions of §§ 145.63(d)(4) or 145.79(e)(4) of this chapter. However, the responsibility for ensuring compliance with the provisions of this

section may not be delegated by the part 135 certificate holder. The part 135 certificate holder shall receive a copy of each report.

14. Section 135.416 is added to read as follows:

§ 135.416 Structural difficulty reports.

(a) Each certificate holder shall report the occurrence or detection of each failure or defect of each primary structure or principal structural element as defined in the manufacturer's Maintenance Manual (which includes the aircraft's Structural Repair Manual and other manufacturer's documents that set forth maintenance requirements) related to—

(1) Corrosion that requires rework or blendout that exceeds the manufacturer's Maintenance manual (MM) allowable limits and requires a repair or a complete or partial replacement of a primary structure or principal structural element;

(2) Cracks that require a repair or a complete or partial replacement of a primary structure or principal structural element;

(3) Disbonding that requires a repair or a complete or partial replacement of a primary structure or principal structural element;

(4) Failures or defects repaired in accordance with Designated Engineering Representative (DER) data or other approved data not contained in the manufacturer's MM; and

(5) Any crack, fracture, or delamination of a primary structure or principal structural element composed of composite materials.

(b) In addition to the reports required by paragraph (a) of this section, each certificate holder shall report any other failure or defect in aircraft structure that occurs or is detected at any time if, in its opinion, that failure or defect has endangered or may endanger the safe operation of any aircraft it uses.

(c) Each certificate holder shall submit each report required by this section, as prescribed in paragraphs (a) and (b) of this section, covering each 24-hour period beginning at 0900 local time of each day and ending at 0900 local time on the next day, to a centralized collection point as specified by the FAA. Each certificate holder also shall make the report data available for examination by the Flight Standards District Office charged with the overall inspection of the certificate holder in a form and manner acceptable to the Administrator. Each report of occurrences during a 24-hour period shall be submitted to the FAA within the next 72 hours. However, a report that is due on Saturday or Sunday may be submitted on the following Monday, and one that is due on a holiday may be submitted on the next work day. For aircraft operating in areas where mail is not collected, reports may be submitted within 24 hours after the aircraft returns to a point where the mail is collected.

(d) The certificate holder shall submit the reports required by this section in an electronic form or another form acceptable to the Administrator. The reports must include the information listed in paragraphs (d)(1) through (d)(6) of this section and should include as much information that is reasonably available for paragraph (d)(7) of this section:

(1) Manufacturer, model, serial number, and registration number of the aircraft.

(2) The name of the operator.

(3) The nature of the failure or defect and its location.

(4) The FAA-modified Air Transport Association Specification 100 code (ATA code).

(5) The aircraft total time and cycles.

(6) The date and station where the failure or defect was discovered.

(7) Identification of the part or component involved (e.g., manufacturer's part number and serial number) and the time since the last maintenance overhaul, repair, or inspection.

(e) A certificate holder that is also the holder of a Type Certificate (including a Supplemental Type Certificate), a Parts Manufacturer Approval (PMA), or a Technical Standard Order (TSO) authorization or that is a licensee of a Type Certificate need not report a failure, malfunction, or defect under this section if it has reported the failure, malfunction, or defect under § 21.3 of this chapter or under the accident reporting provisions of part 830 of the regulations of the National Transportation Safety Board.

(f) Reports prescribed in paragraph (d) of this section may be submitted by a certificated repair station when the reporting task has been assigned by the part 135 certificate holder under the provisions of §§ 145.63(d)(4) or 145.79(e)(4) of this chapter. However, the responsibility of ensuring compliance with the provisions of this section may not be delegated by the part 135 certificate holder. The part 135 certificate holder shall receive a copy of each report.

15. Section 135.417 is revised to read as follows:

§ 135.417 Mechanical interruption summary report.

Each certificate holder shall regularly and promptly submit a summary report to the Administrator following each interruption to a flight, unscheduled change of aircraft en route, or unscheduled stop or diversion from a route, caused by a known or suspected mechanical difficulty or malfunction that is not required to be reported under § 135.415 or § 135.316.

PART 145—REPAIR STATIONS

16. The authority citation for part 145 is revised to read as follows:

Authority: 49 U.S.C. app. 1354(a), 1355, 1421, and 1427.

17. Section 145.63 is amended by adding paragraphs (d) and (e) to read as follows:

§ 145.63 Reports of defects or unairworthy conditions.

* * * * *

(d) A certificated domestic repair station may submit an operational or structural difficulty report for—

(1) A part 121 certificate holder under § 121.703(g) or § 121.704(g) provided that the report meets the requirements of §§ 121.703(d) and 121.703(e) or §§ 121.704(d) and 121.704(e) of this chapter, as appropriate;

(2) A part 125 certificate holder under § 125.409(g) or § 125.410(g) provided that the report meets the requirements of §§ 125.409(d) and 125.409(e) or §§ 125.410(d) and 125.410(e) of this chapter, as appropriate;

(3) A part 127 certificate holder under § 127.313(g) or § 121.314(g) provided that the report meets the requirements of § 127.313(d) or § 127.313(e) or §§ 127.314(d) and 127.314(e) of this chapter, as appropriate; or

(4) A part 135 certificate holder under § 135.415(g) or § 135.416(g) provided that the report meets the requirements of §§ 135.415(d) and 135.415(e) or §§ 135.416(d) and 135.416(e) of this chapter, as appropriate.

(e) A certificated domestic repair station authorized to report a failure, malfunction, or defect under paragraph (d) of this section need not report the same failure, malfunction, or defect under paragraph (a) of this section. A copy of the report submitted under paragraph (d) of this section shall be forwarded to the certificate holder.

18. Section 145.79 is amended by adding paragraphs (e) and (f) to read as follows:

§ 145.79 Records and reports.

* * * * *

(e) A certificated foreign repair station may submit an operational or structural difficulty report for—

(1) A part 121 certificate holder under § 121.703(g) or § 121.704(g) provided

that the report meets the requirements of §§ 121.703(d) and 121.703(e) or §§ 121.704(d) and 121.704(e) of this chapter, as appropriate;

(2) A part 125 certificate holder under § 125.409(g) or § 125.410(g) provided that the report meets the requirements of §§ 125.409(d) and 125.409(e) or §§ 125.410(d) and 125.410(e) of this chapter, as appropriate;

(3) A part 127 certificate holder under §§ 127.313(g) or 121.314(g) provided that the report meets the requirements of §§ 127.313(d) and 127.313(e) or §§ 127.314(d) and 127.314(e) of this chapter, as appropriate; or

(4) A part 135 certificate holder under §§ 135.415(g) or 135.416(g) provided that the report meets the requirements of §§ 135.415(d) and 135.415(e) or §§ 135.416(d) and 135.416(e) of this chapter, as appropriate.

(f) A certificated domestic repair station authorized to report a failure, malfunction, or defect under paragraph (d) of this section need not report the same failure, malfunction, or defect under paragraph (a) of this section. A copy of the report submitted under paragraph (d) of this section shall be forwarded to the certificate holder.

Issued in Washington, DC, on August 4, 1995.

William J. White,

Acting Director, Flight Standards Service, AFS–1.

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Part V

Department of Housing and Urban Development

24 CFR Part 300 et al.

GNMA—Streamlining Existing Regulations and Implementation of Issuer Eligibility and Integrity Reforms; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Government National Mortgage Association

24 CFR Parts 300, 310, 320, 330, 340, 350, 360, 370, 380, 390, and 395

[Docket No. FR–2908–F–02]

RIN: 2503–AA07

GNMA—Streamlining Existing Regulations and Implementation of Issuer Eligibility and Integrity Reforms

AGENCY: Government National Mortgage Association, HUD.

ACTION: Final rule.

SUMMARY: The Government National Mortgage Association (the ''Association'' or ''GNMA'') is revising its regulations to remove references to terminated programs, place proper emphasis on the Association's current programs, remove obsolete references and simplify the language of all remaining sections.

In addition, this publication implements a revision to the regulations that prescribe the standards by which issuers are approved to participate in the Association's Mortgage-Backed Securities (MBS) program, and by which approved issuers maintain their approval status, which was initiated by a proposed rule published in 1993.

EFFECTIVE DATE: September 13, 1995.

FOR FURTHER INFORMATION CONTACT: Guy S. Wilson, Vice President, Government National Mortgage Association, Room 6151, 451 Seventh Street SW, Washington, DC 20410–9000, telephone (202) 401–8970. Hearing or speech-impaired individuals may call HUD's TDD number (202) 708–3649. (These telephone numbers are not toll free.)

SUPPLEMENTARY INFORMATION:

I. Background

A. Streamlining Existing Regulations

By the direction of the President, the Association performed a page-by-page review of its existing regulations to eliminate or revise those regulations that are outdated or otherwise in need of reform. The Association is revising the entirety of the GNMA rules, which are found in the 300 series in title 24 of the Code of Federal Regulations. This rule removes outdated parts and sections of parts to trim the Association's regulations to only those necessary to operate current programs. Other than as noted below, substantive changes are not intended by virtue of the revisions included herein.

The former 24 CFR parts 320, 330, 340, 350, 360 and 370 have been eliminated, because the programs formerly regulated under those sections have been abolished. The former 24 CFR part 380, Fiduciary Activities, has been moved to 24 CFR part 340. The former 24 CFR part 390, Guaranty of Mortgage-Backed Securities, has been moved to 24 CFR part 320, to reflect its status as the most active of the Association's programs. The former Part 395, Guaranty of Multiclass Securities, has been moved to Part 330 to reflect its status as a program that flows directly from the mortgage-backed securities program. The Bylaws of the Association are no longer published as an appendix to 24 CFR part 310, but will be kept current in the Office of the President of the Association and may be published in the GNMA I Mortgage-Backed Securities Guide and the GNMA II Mortgage-Backed Securities Guide (collectively, the ''GNMA Guides'').

With respect to these streamlining changes, the publication of a final rule without previous solicitation of public comment is justified, in accordance with 24 CFR part 10, because solicitation of public comment is unnecessary and would be contrary to the public interest. The types of changes being made are not controversial or substantive. It is in the public interest to have succinct regulations that reflect only the provisions needed to operate current programs. Therefore, solicitation of public comment before adoption of these changes is unnecessary, and the associated delay in effectiveness would be contrary to the public interest.

1. Part 300

Section 300.1

The reference to regional offices has been removed. All of the Association's business is conducted out of one office.

Section 300.3

The references to the Association purchasing, servicing and selling mortgages has been removed. The Association no longer conducts this business. A reference is added clarifying that the Association is commonly referred to as Ginnie Mae or GNMA.

Section 300.9

All references to carrying on the Association's business through the Federal National Mortgage Association (Fannie Mae) have been removed. None of the Association's business is carried out by Fannie Mae.

Section 300.11

This section has been added to notify the public of the authority of the officers of the Association. This authority is set forth in the Bylaws of the Association, which were formerly published as an appendix to the regulations. This appendix is being removed, necessitating the addition of this section.

Section 300.13 (formerly Section 300.11)

This section has been streamlined by removing the laundry list of actions that may be undertaken by an attorney-in-fact for the Association. The section as rewritten provides that the Association may appoint attorneys-in-fact by publication in the **Federal Register** or by written document executed by the President of the Association and that such attorney-in-fact shall have the power outlined in the publication or appointment.

Section 300.17 (formerly Section 390.60)

This section has been moved from the former Subpart E, Miscellaneous Provisions, to Subpart A, General Provisions, in order to provide a better organizational structure to the regulations. It has also been revised to clarify that audits and examinations may be performed by designees of the Association.

2. Part 310

The Bylaws of the Association, formerly an appendix to Part 310, have been removed. The Bylaws will be maintained in the Office of the President of the Association and may be published in the GNMA I Mortgage-Backed Securities Guide and the GNMA II Mortgage-Backed Securities Guide.

3. Former Parts 320, 330, 340 and 350

These parts have been eliminated because the authority for the Association's Special Assistance Functions (implemented by Subchapter B of Chapter III, Special Assistance Functions, containing these parts) was repealed by section 483(a) of Pub. L. 98–181, approved November 30, 1983, 97 Stat. 1240.

4. Parts 360 and 370

These parts (contained in Subchapter C of Chapter III, Management and Liquidating Functions) have been eliminated because the Association no longer performs Management and Liquidating Functions.

5. Part 320 (formerly Part 390)

The former part 390 has been moved to this part to reflect its status as the most active of the Association's programs.

Sections 320.1, 320.5 and 320.13 (formerly Sections 390.1, 390.5 and 390.13)

These sections have been amended to remove reference to ''straight pass through'' securities, which are no longer guaranteed by the Association.

Section 320.15 (formerly Section 390.15)

This section has been amended to remove reference to ''straight pass through'' securities, which are no longer guaranteed by the Association. This section also has been amended to remove the specific procedures followed by the Association upon the declaration of a default. To the extent necessary, these procedures are outlined in the Guides and/or the guaranty agreement with the issuer.

6. Part 330 (formerly part 395)

The former part 395, Multiclass Securities, has been moved to part 330, following part 320 dealing with the mortgage-backed securities program, to reflect its status as a program that flows directly from the mortgage-backed securities program. Some language has been removed because it is duplicative of language in Parts 300 and 320.

B. Issuer Eligibility and Integrity Reforms

On December 9, 1993 (58 FR 64713), the Department published a proposed rule to reform the Association's issuer eligibility and integrity requirements for new issuer approval and maintenance of approved issuer status. A total of nine comments were received. The commenters included one approved issuer, one mortgage company, one federal savings bank, the Federal Home Loan Mortgage Corporation (Freddie Mac), the Federal Deposit Insurance Corporation (FDIC), the Office of Thrift Supervision (OTS), the Office of the Comptroller of the Currency (OCC), the Independent Bankers Association of America and the Mortgage Bankers Association of America.

The commenters expressed general support for the Department's objectives of strengthening the issuer requirements. The commenters were especially supportive of the closer alignment of the Association's rules with those of Fannie Mae and Freddie Mac, and they expressed a desire for GNMA to continue in that direction. Some commenters opposed parts of the proposed rule, and some provided specific suggestions for changes. On the basis of these comments and further development of the concepts set forth in the proposed rule, the Department has made changes to the rule. These Changes are discussed in the following sections of this preamble.

1. Section 320.3 (formerly Section 390.3) Eligible Issuers

There were four commenters on the paragraph dealing with Fannie Mae and Freddie Mac approval (former Section 390.3(a)(2), including Freddie Mac. Currently, Fannie Mae approval is required for program entry for single family issuers. This section proposed to include Freddie Mac approved seller/servicers as applicants and to limit the Fannie Mae/Freddie Mac approval requirement to single family issuer applicants. While all comments on the proposed language were favorable, certain changes have been made as a result of the Association's own continued analysis of this section. The Association has decided to open its mortgage-backed securities program to issuers without Fannie Mae or Freddie Mac approval. Under the final rule, the Association will consider all applicants, although Fannie Mae and/or Freddie Mac approved applicants will be given special consideration in the approval process. Applicants with neither Fannie Mae nor Freddie Mac approval will be subject to a more stringent set of requirements to provide additional assurances that they are capable of performing the responsibilities of an issuer. These requirements will be set out in the applicable Guides.

The phrase limiting the applicability of this section to single family issuers has been dropped, since an alternative is now being provided to the Fannie Mae/Freddie Mac approval requirement. After an issuer is accepted into the MBS program, loss of either Fannie Mae or Freddie Mac approval continues to remain a basis for issuer default even in cases where the issuer qualified for program entry without Fannie Mae or Freddie Mac approval. In summary, as a result of further analysis, this section is being republished to reflect that (1) this section is applicable to all issuer types, and (2) Association approval is an acceptable alternative to Fannie Mae/Freddie Mac approval. [Note: The ''or the Association'' language in the original regulations referred to the Tandem program which has been terminated.]

There were two commenters on the paragraph dealing with capacity to issue and service (former Section 390.3(a)(3). One comment agreed with the changes. The other commenter wants to expand the scope of the rule to allow the sale of servicing on pooled loans without requiring a change of issuer. The commenter stated that this would eliminate the mortgage assignment costs currently incurred when servicing is sold and the issuer is substituted. Issuers may presently (1) service their pools themselves, (2) obtain subservicers for their pools, while remaining the issuer of record with full responsibility for those pools, (3) act as a subservicer for another issuer's pools, or (4) transfer issuer responsibility (and servicing) to another issuer. The Association believes these options give issuers the flexibility to manage their business while providing the Association with an adequate level of risk protection. The purpose of this section of the rule is to formally recognize that an issuer may choose to act as an issuer of pools or servicer or both. The Association is not prepared to make a major scope change to the rule to permit the sale of servicing without a change in issuer. Therefore the servicing language is not being changed. This section of the rule, however, is being republished with a minor change to clarify that the experience of the management of an issuer is a criterion for issuer eligibility.

There were three commenters on increasing the single family base net worth requirement to $250,000. One commenter stated that the increase would be too costly for small lenders, while the other two commenters, both trade associations, agreed with the increase. One of these trade associations requested that GNMA consider special net worth requirements for small and minority lenders, and the other stated that the $250,000 level would ''increase the safety of the program yet not prohibit smaller institutions from participating.''

There were two commenters on the requirement to index base Net Worth for inflation (former Section 390.3). One commenter generally agreed with the indexing. The other commenter questioned the need for indexing. It believes that the incremental component of net worth already takes inflationary concerns into account, and that smaller issuers may be adversely affected. It also requested that if indexing is implemented, that the Association (1) phase-in indexing over a minimum of 6 months, (2) reconsider whether the consumer price index (CPI) is the appropriate index, (3) allow decreases for inflation as long as the new value is not below $250,000, and (4) place an annual cap on the potential increase.

The Association agrees that there are numerous factors to be considered in determining how the net worth element is implemented, and the impact on smaller issuers is certainly an important consideration. Since economic factors

influencing appropriate net worth requirements change regularly, the Association has determined that in the spirit of streamlining its regulations and to provide as much flexibility as possible to the issuer qualification process, net worth requirements will not be published as regulations, but will be published in the GNMA Guides.

2. Former Section 390.12

There was one comment on the provisions concerning control changes (formerly § 390.12(c)), which was in agreement with the language. While the only comment was favorable, upon the Association's own internal analysis of this section, it was decided that both the time requirement pertaining to the notification of change and the definition of what constitutes a change in control be placed in the applicable Guides, rather than in the regulations. Therefore, this section is being republished with changes to (1) remove the 30 day requirement, and (2) remove the Generally Accepted Accounting Practices (GAAP) definition.

There were five commenters on the provisions concerning cross-default agreements (formerly § 390.12(d)). One commenter agreed with the language. Another commenter expressed concern that the agreement may not be consistent with the requirements of some Federal regulators. In addition, this commenter requested that (1) the general terms of the agreement be open to public comment, and (2) both entry into and enforcement of a cross-default agreement be waived when it can be proved that related companies have been operated independently in a safe and sound manner such that there is no attempt to defraud the Association. The other three commenters were the FDIC, OTS, and OCC. FDIC and OTS also included an attachment with their comments from the Federal Reserve Board. All of these Federal agencies believe that cross-default agreements may not be consistent with section 23A of the Federal Reserve Act which contains limitations and collateralization requirements on guaranties between depository institutions and affiliates.

Based on meetings and discussions with the four Federal regulators, the Association has modified the rule language to allow for an exemption from the cross-default agreement when an issuer can provide an acceptable legal opinion that demonstrates that the agreement would be prohibited by the issuer's Federal regulator. While Section 23A was considered in the Association's analysis, the primary reason for the exemption is that the Association's experience to date has demonstrated that regulated issuers present less of a default risk than non-regulated issuers. Furthermore, based on additional analysis, this section has been revised to remove the GAAP (Generally Accepted Accounting Principles) definition of related issuers (detailed guidance will be provided in the Guides), and to provide for the option of default rather than the obligation to default. In summary, this section is being republished with changes to (1) provide a possible exemption for certain classes of Federally regulated issuers, (2) remove the GAAP definition, and (3) provide for the option of default.

3. Section 320.10 Classified Balance Sheet

There was one comment on this section, which was in agreement with the proposed language. This section is being republished without any changes.

4. Section 320.12 Integrity

There were two comments on the provisions concerning key personnel (§ 320.12(a)), and both were in agreement with the proposed language. This section is being republished with a minor change to clarify that local agencies are included with Federal, state, and government-related entities in respect to required disclosures of key personnel backgrounds.

There were four comments on the provisions concerning status with other agencies (section 320.12(b)). Two of the comments were in agreement with the proposed language. The commenters with concerns were the FDIC and OCC. These federal agencies stated that certain disclosures may be prohibited under their respective regulations. The FDIC also expressed concern that if issuers were to disclose FDIC actions, the agency's ability to promote safety may be impaired. The Association believes that notice of agency actions will enhance its ability to monitor issuers, and that cooperation between Federal agencies is necessary to properly protect the Government's interest. However, the Association believes that it should not compel issuers to make disclosures that are specifically prohibited by other agencies. Therefore, this section is being republished with a change to reflect that disclosures that are specifically prohibited by agencies are exempted from this section. Furthermore, the section is also being amended to clarify that state and local mortgage and regulatory agencies are included as covered parties requiring issuer disclosure of material status changes.

II. Other Matters

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this rule before publication and, by approving it, certifies that this rule does not have a significant economic impact on a substantial number of small entities. The eligibility and performance requirements of this rule are consistent with requirements already established by other government agencies for lender eligibility. Accordingly, the economic impact of this rule would be minimal, and it is expected to affect small and large entities equally.

Environmental Impact

A Finding of No Significant Impact with respect to the environment was made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332) in connection with the development of the proposed rule. The Finding of No Significant Impact remains applicable to this final rule, and is available for public inspection and copying Monday through Friday, 7:30 a.m. until 5:30 p.m. in the office of the Rules Docket Clerk, Office of General Counsel, room 10276, 451 Seventh Street, SW, Washington, DC 20410.

Regulatory Agenda

The issuer eligibility and integrity reforms portion of this rule was listed as sequence number 1501 in the Department's Semiannual Agenda of Regulations published on May 8, 1995 (60 FR 23368, 23396) in accordance with Executive Order 12866 and the Regulatory Flexibility Act.

Executive Order 12612, Federalism

The General Counsel, as the Designated Official under section 6(a) of Executive order 12612, Federalism, has determined that the policies contained in this rule do not have federalism implications and, thus, are not subject to review under the Order. This rule is limited to streamlining existing regulations and imposing additional eligibility and integrity requirements on private lenders. No programmatic or policy changes result from its promulgation which would affect existing relationship between the Federal government and State and local governments.

Executive Order 12606, The Family

The General Counsel, as the Designated Official under Executive

Order 12606, The Family, has determined that this rule does not have a potential significant impact on family formation, maintenance, and general well-being, and, thus, is not subject to review under the Order. No significant change in existing HUD policies or programs, as those policies relate to family concerns, will result from promulgation of this rule.

List of Subjects

24 CFR Part 300

Lawyers, Organization and functions (Government agencies).

24 CFR Part 310

Organization and functions (Government agencies).

24 CFR Parts 320, 330, 340, 350, and 370

Mortgages.

24 CFR Part 360

Mortgages, Trusts and trustees.

24 CFR Part 380

Mortgages, Trusts and trustees.

24 CFR Part 390

Mortgages, Securities.

Accordingly, Chapter III of Title 24 of the Code of Federal Regulations is amended as follows:

1. The subchapter designations and headings are removed from the chapter.

2. Part 300 is revised in its entirety, to read as follows:

PART 300—GENERAL

Sec.
300.1 Scope of chapter.
300.3 Description.
300.5 Creation and status.
300.7 Area of operations.
300.9 Office.
300.11 Authority of officers.
300.13 Power of attorney.
300.15 Exceptions.
300.17 Audits and reports.

Authority: 12 U.S.C. 1723a, unless otherwise noted, and 42 U.S.C. 3535(d).

§ 300.1 Scope of chapter.

This chapter consists of general information and does not purport to set forth all of the procedures and requirements that apply to the operations of the Association. Complete specific information as to any aspect of such operations may be obtained from the office listed in § 300.9.

§ 300.3 Description.

The Government National Mortgage Association (hereinafter in this chapter called the Association) furnishes fiduciary services to itself and other departments and agencies of the Government, and guarantees privately issued securities backed by trusts or pools of mortgages or loans which are insured or guaranteed by the Federal Housing Administration (FHA), the Department of Veterans Affairs (VA) or the Farmers Home Administration (FmHA). In the course of its business, the Association is commonly referred to as Ginnie Mae or GNMA.

§ 300.5 Creation and status.

The Association is a Government corporation in the Department of Housing and Urban Development. It is derived from the Federal National Mortgage Association, which was partitioned by the Congress into two corporations effective September 1, 1968, one of which is the Association. The operations of the Association are conducted under its statutory charter contained in title III of the National Housing Act, 12 U.S.C. 1716, *et seq.*

§ 300.7 Area of operations.

The Association is authorized to conduct its business in any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, and the territories and possessions of the United States.

§ 300.9 Office.

The Association directs its operations from its office located at 451 Seventh Street, SW., Washington DC 20410.

§ 300.11 Authority of officers.

The President, each Vice President, and each Assistant Vice President of the Association are severally expressly empowered in the name of the Association to sign all contracts and other documents, instruments, and writings which call for execution by the Association in the conduct of its business and affairs, and to encumber, mortgage, pledge, convey or otherwise alien any property which the Association may own or in which it may have an estate, right, title or interest. In addition, the President, each Vice President, each Assistant Vice President, the Secretary of the Association, each Assistant Secretary, the Treasurer and the Controller shall have the authority as may be provided in the Bylaws of the Association or as may be delegated to them in a manner not inconsistent with the Bylaws.

§ 300.13 Power of attorney.

In order to efficiently carry out the purposes of the Association, the Association may appoint any person its true and lawful attorney-in-fact by publication in the **Federal Register** or by appointment from the President of the Association in writing. Any such attorney-in-fact shall have the power outlined in the publication or appointment.

§ 300.15 Exceptions.

In the conduct of its affairs, in individual cases or classes of cases, the Association reserves the right, consistent with law, without prior notice and at any time, to alter or waive any of the requirements contained in this chapter or elsewhere or to impose other and additional requirements; it further reserves the right, without prior notice and at any time, to amend or rescind any or all of the material set forth herein.

§ 300.17 Audits and reports.

The Association and its designees may at any reasonable time audit the books and examine the records of any issuer, mortgage servicer, trustee, agent or other person bearing on compliance with the requirements of the Association's programs, and the Association may require reasonable and necessary reports from such persons.

3. Part 310 consisting of § 310.1 is revised in its entirety, to read as follows:

PART 310—BYLAWS OF THE GOVERNMENT NATIONAL MORTGAGE ASSOCIATION

Authority: 12 U.S.C. 1723 and 42 U.S.C. 3535(d).

§ 310.1 Bylaws of the Association.

The bylaws of the Association shall be duly adopted by the Secretary of Housing and Urban Development pursuant to section 308 of the National Housing Act (12 U.S.C. 1723) and shall govern the performance of the powers and duties granted to or imposed upon the Association by law.

4. Part 320 is revised in its entirety, to read as follows:

PART 320—GUARANTY OF MORTGAGE-BACKED SECURITIES

Subpart A—Pass-Through Type Securities

Sec.
320.1 General.
320.3 Eligible issuers of securities.
320.5 Securities.
320.7 Mortgages.
320.9 Pool administration.
320.10 Financial reporting.
320.11 Insurance coverage.
320.12 Integrity.
320.13 Guaranty.
320.15 Default.
320.17 Fees.

Subpart B—Bond-Type Securities

320.21 General.
320.23 Eligible issuers.

320.25 Securities.
320.27 Mortgages.
320.29 Guaranty.
320.31 Default.
320.33 Fees.

Authority: 12 U.S.C. 1721(g) and 1723a(a); and 42 U.S.C. 3535(d).

Subpart A—Pass-Through Type Securities

§ 320.1 General.

The Association is authorized by section 306(g) of the National Housing Act (12 U.S.C. 1721(g)) upon such terms and conditions as it may deem appropriate, to guarantee the timely payment of principal of and interest on securities that are based on and backed by a trust or pool composed of mortgages which are insured or guaranteed by FHA, FmHA or VA. The Association's guaranty of mortgage-backed securities is backed by the full faith and credit of the United States. This subpart is limited to ''modified pass-through'' securities, and does not purport to set forth all the procedures and requirements that apply to the issuance and guaranty of such securities. All such transactions are governed by the specific terms and provisions of the Association's Mortgage-Backed Securities Guides (MBS Guides) and contracts entered into by the parties.

§ 320.3 Eligible issuers of securities.

(a) *Eligibility requirements.* A mortgage lender, including an instrumentality of a State or local government, to be eligible to issue or service mortgage-backed securities guaranteed by the Association must satisfy all of the following standards:

(1) Be in good standing as a mortgagee approved by the FHA;

(2) Be in good standing as a mortgage seller or servicer approved by the Federal National Mortgage Association (FNMA), the Federal Home Loan Mortgage Corporation (FHLMC), or the Association. Loss of either FNMA approval or FHLMC approval may cause the issuer to become ineligible to issue and service the Association's mortgage-backed securities and constitute a default under the applicable guaranty or contractual agreement whether or not the issuer qualified for new issuer approval on the basis of FNMA or FHLMC approval;

(3) Have management with adequate experience, and access to adequate facilities to issue or service mortgage-backed securities, as determined by the Association;

(4) Maintain the applicable minimum net worth discussed in paragraph (c) of this section; and

(5) Meet the requirements, conditions, and limitations prescribed by the Association in this part or the applicable MBS Guides.

(b) *Time of eligibility.* The Association shall not commit to guarantee, or guarantee any issue of mortgage-backed securities unless the mortgage lender requesting such commitment or guaranty qualifies as an eligible issuer both at the time of commitment approval and at the time of the issuance of the guaranty.

(c) *Net worth requirements.* Issuers shall maintain at all times a net worth acceptable to the Association of not less than the applicable minimum amount. The applicable minimum amount shall be published in the MBS Guides.

(d) *Disqualification.* A mortgage lender shall not qualify as an eligible issuer at any time in which:

(1) The lending policies of the issuer permit any discrimination based on race, religion, color, national origin, age, or sex of a borrower; or

(2) The issuer is not in compliance with any rules, regulations, or orders issued under title VI of the Civil Rights Act of 1964; Executive Order 11063, Equal Opportunity in Housing, November 20, 1962; Executive Order 11246, Equal Employment Opportunity, issued on September 24, 1965 and amended on October 13, 1967; title VII of the Civil Rights Act of 1968; title VIII of the Civil Rights Act of 1968 as amended by the Fair Housing Amendments Act of 1988; or by the FHA or VA.

(e) *Ethics and standards.* A mortgage lender shall qualify as an eligible issuer only so long as it conducts its business operations in accordance with accepted mortgage banking practices, ethics, and standards, as determined by the Association, and maintains its books and records in accordance with generally accepted accounting principles.

(f) *Change in control.* Issuers shall notify the Association of any change in issuer control. A change in control occurs whenever a new party obtains significant influence over an issuer, as defined by the Association. In a merger where the surviving party is not the approved issuer and in a consolidation, the surviving party must apply formally for approval as a new issuer prior to the merger or consolidation taking place. In other business combinations, such as a stock sale of an existing issuer, which result in a change in control of issuer, the issuer shall demonstrate that it continues to meet all issuer eligibility requirements prior to the business combination being finalized.

(g) *Cross-Default.* Related issuers, as defined by the Association, shall execute a cross-default agreement, in a form prescribed by the Association, that authorizes the default of one or more related issuers in the event of a default by any one of the related issuers. Issuers may be granted an exemption from this section, provided that they submit a legal opinion, acceptable to the Association, which demonstrates that the execution of a cross-default agreement would be prohibited by the issuer's Federal regulator.

(h) *Failure to comply.* In the event that an issuer subsequently fails to comply with any of the requirements prescribed in this part or the applicable MBS Guide, as determined by the Association, the Association may, among other things, withhold further commitments to guarantee securities until such time as the Association is satisfied that the issuer has resumed business operations in compliance with such requirements.

(Approved by the Office of Management and Budget under control numbers 2503–0003, 2503–0004, 2503–0006, 2503–0007, and 2503–0026)

§ 320.5 Securities.

(a) *Instruments.* Securities issued pursuant to the provisions of this subpart must be modified pass-through securities, that provide for payment, whether or not collected, of both specified principal installments and interest on the unpaid principal balance, with all prepayments and other unscheduled recoveries of principal being passed through to the holder. In the case of delinquent mortgages in a pool backing modified pass-through securities, the issuer is required to make advances if necessary to maintain the specified schedule of interest and principal payments to the holders, or at its option, at any time 90 days or more after default of any such mortgage, the issuer may repurchase such mortgage for an amount equal to the unpaid principal balance of the mortgage. The securities must specify the dates by which payments are to be made to the holders thereof, and must indicate the accounting period for collections on the pool's mortgages relating to each such payment, and the securities must also specify a date on which the entire principal will have been paid or will be payable.

(b) *Issue amount.* Each issue of guaranteed securities must be in a minimum face amount as specified in the applicable MBS Guide. The total face amount of any issue of securities cannot exceed the aggregate unpaid principal balances of the mortgages in

the pool. The Association may provide for issuers to submit packages of mortgages that may be consolidated, with other packages of similar types of mortgages, into multiple issuer pools.

(c) *Face amount of securities.* The face amount of any security cannot be less than $25,000.

(d) *Transferability.* Securities are transferable, but the share of the proceeds collected on account of the pool of mortgages is payable only to the registered holder of a security according to the policies established by the Association.

§ 320.7 Mortgages.

Each issue of guaranteed securities must be backed by a separate pool of mortgages which meet the requirements of the applicable MBS Guide.

§ 320.9 Pool administration.

The Association will only guarantee securities if the issuer executes a guaranty agreement or contractual agreement in the form prescribed by the Association. Pool administration requirements are set forth in such agreements or the applicable MBS Guide.

(Approved by the Office of Management and Budget under control numbers 2503–0003, 2503–0004, 2503–0006, 2503–0007, and 2503–0026)

§ 320.10 Financial reporting.

Issuers shall submit to the Association audited annual financial statements within 90 days of their fiscal year end. All financial statements with a fiscal year end date on or after [one year after the effective date of this rule] shall include a classified balance sheet and a statement of operations and cash flows, prepared in accordance with the standards for financial audits of the U.S. General Accounting Office's *Government Auditing Standards,* issued by the Comptroller General of the United States. The balance sheet shall show the division of total assets into current, noncurrent and fixed assets and the division of total liabilities into current and long-term liabilities.

§ 320.11 Insurance coverage.

The issuer shall maintain, for the benefit of the Association, insurance, errors and omissions, fidelity bond and other coverage as required by the Association and set forth in the appropriate MBS Guide.

§ 320.12 Integrity.

(a) *Background.* Issuers shall disclose the background of all individuals serving on their Board of Directors and all individuals acting as authorized signatories. The disclosures shall include any prior convictions, fines or other adverse actions against these individuals by a Federal, state or local agency, or a government-related entity where the action is related to the responsibilities that are commensurate with those of the financial services industry. The term government-related entity includes, but is not limited to, FHA, VA, FmHA, FNMA, FHLMC, Office of Thrift Supervision, Federal Deposit Insurance Corporation, Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, and National Credit Union Administration.

(b) *Change in status.* Issuers shall disclose material changes in their status with other government-related entities and regulatory agencies, or state or local agencies with similar authority, within 5 business days of their occurrence. The disclosures shall include, but not be limited to, voluntary and non-voluntary terminations, defaults, fines, and material non-compliance with agency rules and policies. Disclosures that are specifically prohibited by an agency are exempted from this section.

§ 320.13 Guaranty.

The Association guarantees the timely payment, whether or not collected, of the interest on the outstanding balance and the specified principal installments, as undertaken in the Association's guaranty appearing on the face of the security. The Association's guaranty is backed by the full faith and credit of the United States.

§ 320.15 Default.

(a) *Issuer default.* Any failure or inability of the issuer to make payments as due as well as such other events as may be identified by the Association and included in the applicable guaranty agreement, contractual agreement or MBS Guide, shall constitute a default of the issuer.

(b) *Action upon default.* Upon any default by the issuer, the Association may:

(1) Institute a claim against the issuer's insurance, bond or other coverage, as specified in § 320.11;

(2) Pursuant to section 306(g) of the National Housing Act (12 U.S.C. 1721(g)), extinguish all the right, title, or other interest of the issuer in the pooled mortgages; and

(3) Exercise such other rights and remedies as it may have.

§ 320.17 Fees.

The Association may impose application fees, guaranty fees, securities transfer fees and other fees.

Subpart B—Bond-Type Securities

§ 320.21 General.

In addition to the ''pass-through'' securities dealt with in subpart A of this part, the Association is authorized by section 306(g) of the National Housing Act, 12 U.S.C. 1721(g), upon such terms and conditions as it may deem appropriate, to guarantee the timely payment of principal of and interest on ''bond-type'' securities which are based on and backed by a trust or pool composed of mortgages which are insured or guaranteed by FHA, FmHA or the VA. The Association's guaranty of mortgage-backed securities is backed by the full faith and credit of the United States. This subpart deals with such ''bond-type'' securities and does not purport to set forth all the procedures and requirements that apply to the issuance and guaranty of such securities. All such transactions are governed by the specific terms and provisions of the contracts entered into by the parties and the Bond-Type Securities Guide (the ''Bond Guide'').

§ 320.23 Eligible issuers.

Any corporation, trust, partnership, or other entity with a net worth acceptable to the Association as set forth in the Bond Guide, which has the capability to assemble acceptable and eligible mortgages in sufficient quantity to support required minimum issuances of securities and which meets such other requirements as are set forth in the Bond Guide, may be approved to issue and service bond-type securities guaranteed by the Association. Further, the Association reserves the right to limit the number of issuers in the interest of conducting an orderly market of securities of this type.

§ 320.25 Securities.

(a) *Instruments.* Securities to be issued pursuant to the provisions of this subpart B may be in registered or bearer form. Each security shall have terms acceptable to the Association as provided in the Bond Guide.

(b) *Issue amount.* Each issue of guaranteed securities must be in a minimum face amount as specified in the Bond Guide. The total face amount of any issue of securities cannot exceed the aggregate unpaid principal balances of the mortgages in the pool.

(c) *Face amount of securities.* The face amount of any security cannot be less than $25,000.

(d) *Transferability.* Bearer securities are freely transferrable. Registered securities are transferable only on the books of an agent, as shall be agreed upon by the Association and the issuer.

(e) *Treasury approval.* Issues of $100 million or larger will be subject to approval of the Secretary of the Treasury.

§ 320.27 Mortgages.

Guaranteed securities issued under these provisions must be based on and backed by mortgages pooled under trust arrangements satisfactory to the Association. Such mortgages must meet the requirements of the Bond Guide.

§ 320.29 Guaranty.

With respect to bond-type securities, the Association will guarantee the timely payment of principal of and interest on such securities, subject to the terms and conditions of the securities. The Association's guaranty is backed by the full faith and credit of the United States.

§ 320.31 Default.

Upon default of the issuer, the Association has the right, pursuant to section 306(g) of the National Housing Act (12 U.S.C. 1721(g)), to take title to the mortgages and other assets that are subject to the trust arrangements, and to proceed against other assets of the issuer to the extent necessary to satisfy its own claims and the rights of the holders of securities then outstanding. Such action by the Association shall be taken subject to an accounting to the issuer.

§ 320.33 Fees.

The Association may impose application and guaranty fees, which may vary with relation to the size or risk of the guaranty transaction undertaken.

5. Part 330 is revised in its entirety, to read as follows:

PART 330—GUARANTY OF MULTICLASS SECURITIES

Sec.
330.1 Scope of part.
330.5 Definitions.
330.10 Eligible collateral.
330.15 Participation requirements.
330.20 Eligible participants.
330.25 Fees.
330.30 GNMA guaranty.
330.35 Investors.
330.40 Consultation.
330.45 Limitation on GNMA liability.
330.50 Administration of multiclass securities.
330.55 Basis for removal from participation.
330.60 Removal procedure.

Authority: 12 U.S.C. 1721(g) and 1723a(a); and 42 U.S.C. 3535(d).

§ 330.1 Scope of part.

This part is limited to multiclass securities. It does not purport to set forth all the procedures and requirements that apply to the issuance and guaranty of such securities. All such transactions are governed by the specific terms and provisions of the contracts entered into by the parties and by the GNMA Multiclass Securities Guide (Multiclass Guide).

§ 330.5 Definitions

As used in this part, the following terms shall have the meanings indicated.

Consolidated securities. A series of multiclass securities each class of which provides for payments proportionate with payments on the underlying eligible collateral.

Depositor. The entity that deposits, or executes an agreement to deposit, as contained in the Multiclass Guide, eligible collateral into a trust in exchange for consolidated securities.

GNMA electronic bulletin board. An information distribution system established by the Association for the Multiclass Securities program.

GNMA MBS certificates. The guaranteed mortgage-backed securities issued under part 320 of this chapter.

Government mortgages. Mortgages that are eligible under section 306(g) (12 U.S.C. 1721(g)) for inclusion in GNMA mortgage-backed securities pools.

Participant. For structured securities, the sponsor, co-sponsor, trustee, trust counsel, accounting firm, and their contractors. For consolidated securities, the depositor. Other entities may be designated as participants in the Multiclass Guide.

Sponsor. With respect to structured securities, the entity that establishes the required trust by executing the trust agreement and depositing the eligible collateral in the trust in exchange for the structured securities.

Structured securities. Securities of a series at least one class of which provides for payments of principal or interest disproportionately from payments on the underlying eligible collateral.

§ 330.10 Eligible collateral.

The Association, in its discretion, shall determine what collateral is eligible for inclusion in the Multiclass Securities program. Eligible collateral may include GNMA MBS certificates, government mortgages, consolidated securities, and other securities approved by the Association. Categories of these GNMA MBS certificates, government mortgages, consolidated securities, and other securities as approved by the Association become eligible collateral when they are published as eligible collateral in the Multiclass Guide or on the GNMA electronic bulletin board. Eligible collateral may differ for various Association guaranteed multiclass securities.

§ 330.15 Participation requirements.

To participate in the Multiclass Securities program, a participant must meet the following criteria:

(a) *Certification.* A participant must submit such certifications and other documents as are required by the Multiclass Guide.

(b) *Compliance with Multiclass Guide.* By completing a multiclass securities transaction, a participant is deemed to have represented and warranted to the Association that it has complied with, and that it agrees to comply with, the Multiclass Guide in effect as of the date that the Association's guaranty is placed on the securities.

(c) *Material changes in status.* A participant must report, as required in the Multiclass Guide, material adverse changes in status including voluntary and non-voluntary termination, defaults, fines and findings of material non-conformance with rules and policies of state and federal agencies and federal government sponsored enterprises.

(d) *Integrity.* The participant must conduct its business operations in accordance with industry practices, ethics and standards, and maintain its books and records in an appropriate manner, as determined by the Association.

(Approved by the Office of Management and Budget under control number 2503–0030)

§ 330.20 Eligible participants.

In addition to requirements set forth in this part, a participant must meet the following requirements.

(a) *Structured securities.*—(1) *Description.* The Association guarantees the payment of principal and interest on structured securities issued by trusts organized by sponsors in accordance with procedures established and approved by the Association. The structured securities are backed by eligible collateral, as described in this part, held by the trustee.

(2) *Eligibility requirements for participants.* (i) *Sponsors.* A sponsor must:

(A) Apply and be approved by the Association;

(B) Demonstrate to the satisfaction of the Association its capacity to accumulate the eligible collateral, as described in this part, needed for a proposed structured securities issuance;

(C) Be in good standing with and either have been responsible for at least one structured securities transaction with FNMA or FHLMC, or have demonstrated to the Association's

satisfaction its capability to act as sponsor of GNMA guaranteed structured securities;

(D) Have the minimum required amount, as set forth in the Multiclass Guide, in shareholders' equity or partners' capital, evidenced by the sponsor's audited financial statements, which must have been issued within the preceding 12-month period;

(E) Represent the structural integrity of the issuance under all cash flow scenarios and demonstrate to the Association's satisfaction its ability to indemnify the Association for a breach of this representation;

(F) Comply with the Association's policies regarding participation by minority and/or women-owned businesses and take appropriate measures to assure compliance by the other participants as specified in the Multiclass Guide; and

(G) Provide the Association with the opinions of trust counsel and accounting firms which are acceptable to the Association and on which the Association may rely.

(ii) *Co-sponsors.* A Co-sponsor must submit to the Association an application and a certification, as set forth in the Multiclass Guide, as to its status as a minority and/or women-owned business.

(iii) *Trustees.* A trustee is selected by the Sponsor from institutions approved by the Association using such procedures as the Association deems appropriate.

(b) *Consolidated securities.* (1) *Description.* A Depositor delivers, or executes an agreement to deliver, eligible collateral to a trust in exchange for a single Association guaranteed multiclass security, as set forth in the Multiclass Guide.

(2) *Eligibility requirements for participant.* A Depositor must certify that:

(i) It is an ''accredited investor'' within the meaning of 17 CFR 230.501(a)(1), (a)(3) or (a)(7);

(ii) It has authority to deliver, and will deliver, the collateral to the trustee and that the collateral is free and clear of all liens and encumbrances; and

(iii) The information set forth by the depositor regarding the eligible collateral is true and correct.

(c) *Other types of Association guaranteed multiclass securities.* The Association will set forth the requirements for the guaranty by the Association of other types of multiclass securities, and the eligibility requirements for the appropriate participants, in the Multiclass Guide or on the GNMA electronic bulletin board.

§ 330.25 Fees.

The Association, in its discretion, through publication in the Multiclass Guide or on the GNMA electronic bulletin board, may impose fees for application, guaranty, transfer, change from book entry to certificated form, or other related fees. Fees may vary, at the Association's discretion, depending upon, but not limited to, such factors as size, collateral characteristics, expense or risk of the guaranty transaction undertaken.

§ 330.30 GNMA guaranty.

The Association guarantees the timely payment of principal and interest as provided by the terms of the multiclass security. The Association's guaranty is backed by the full faith and credit of the United States.

§ 330.35 Investors.

Association guaranteed multiclass securities may not be suitable investments for all investors. No investor should purchase securities of any class unless the investor understands, and is able to bear, the prepayment, yield, liquidity and market risks associated with the class. The Association assumes no obligation or liability to any person with regard to determining the suitability of such securities for such investor.

§ 330.40 Consultation.

The Association may consult with persons or entities in such manner as the Association deems appropriate to ensure the efficient commencement and operation of the Multiclass Securities program.

§ 330.45 Limitation on GNMA liability.

Except for its guaranty, the Association undertakes no obligation and assumes no liability to any person with regard to or on account of the existence or operation of this part or the conduct of any participants in the Multiclass Securities program.

§ 330.50 Administration of multiclass securities.

The GNMA guaranteed multiclass securities will be administered in accordance with the Association's requirements described in the Multiclass Guide.

§ 330.55 Basis for removal from participation.

A participant may be removed from the Multiclass Securities program if the Association, in its discretion, determines that any of the following exists or has occurred:

(a) The participant, at any time, fails to meet any condition for eligibility;

(b) The participant fails to comply with any provision of the Multiclass Guide or this part;

(c) The participant is unable or fails to truthfully, correctly or fully submit such certifications as are required; and

(d) Such further reasons as the Association determines necessary to protect the safety and soundness of the Multiclass Securities program, as set out in the Multiclass Guide.

§ 330.60 Removal procedure.

(a) A participant may be suspended from participation in the Multiclass Securities program upon written notice from the Association, which shall include the reasons for the suspension. The participant shall have the opportunity to submit a written presentation to the President of the Association, or designee, in support of its reinstatement, subject to such limitations as the Association in its discretion may impose as to length, time for submission, or otherwise. A determination by the President of the Association, or designee, shall exhaust the participant's administrative remedies.

(b) If a participant is suspended from the Multiclass Securities program, the Association shall have no obligation to complete a pending transaction involving the participant.

(c) After a participant has been removed from the Multiclass Securities program, the participant may request reinstatement. Approval of the reinstatement is at the sole discretion of the Association.

6. Part 340 is revised in its entirety, to read as follows:

PART 340—FIDUCIARY ACTIVITIES

Sec.
340.1 General.
340.3 Appropriations.

Authority: 12 U.S.C. 1723a and 42 U.S.C. 3535(d).

§ 340.1 General.

The Association is authorized by section 302(c) of the National Housing Act (12 U.S.C. 1717(c)) to create, accept, execute, and administer trusts and other fiduciary undertakings appropriate for financing purposes. Under this authority, the Association is authorized to acquire and otherwise deal in any mortgages or other types of obligations in which any department or agency of the United States listed in section 302(c)(2) of such Act may have a financial interest. Under its fiduciary powers, the Association may create, accept, and administer trusts consisting of interests in mortgages and obligations, sell to private investors

certificates of beneficial interest, or participations, in the mortgages or obligations or in the interest and principal payments derived therefrom, and provide for payment of interest and principal and for retirement of the participations. The Association, in its ordinary corporate capacity as contrasted to its fiduciary capacity, is expressly authorized to guarantee the participations.

§ 340.3 Appropriations.

There is authority for Congress to appropriate such sums as may be necessary to enable the trustor of any trust (as described in § 340.1) to pay to the Association, as trustee, any insufficiency in aggregate receipts from the obligations subject to the trust to provide for the timely payment by the trustee of all interest or principal on the beneficial interests or participations related to such trust.

PART 350—[REMOVED]

7. Part 350 is removed.

PART 360—[REMOVED]

8. Part 360 is removed.

PART 370—[REMOVED]

9. Part 370 is removed.

PART 380—[REMOVED]

10. Part 380 is removed.

PART 390—[REMOVED]

11. Part 390 is removed.

PART 395—[REMOVED]

12. Part 395 is removed.

Dated: August 2, 1995.

Dwight P. Robinson,

President, Government National Mortgage Association.

[FR Doc. 95–19968 Filed 8–11–95; 8:45 am]

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federal register

Monday
August 14, 1995

Part VI

The President

Memorandum of August 10, 1995—Facilitating Access to Federal Property for the Siting of Mobile Services Antennas

Federal Register
Vol. 60, No. 156
Monday, August 14, 1995

Presidential Documents

Title 3—

The President

Memorandum of August 10, 1995

Facilitating Access to Federal Property for the Siting of Mobile Services Antennas

Memorandum for the Heads of Departments and Agencies

Recent advancements in mobile telecommunications technology present an opportunity for the rapid construction of the Nation's wireless communications infrastructure. As a matter of policy, the Federal Government shall encourage the efficient and timely implementation of such new technologies and the concomitant infrastructure buildout as a means of stimulating economic growth and creating new jobs. The recent auctioning and impending licensing of radio frequencies for mobile personal communications services presents the Federal Government with the opportunity to foster new technologies and to encourage the development of communications infrastructure by making Federal property available for the siting of mobile services antennas.

Therefore, to the extent permitted by law, I hereby direct the Administrator of General Services, within 90 days, in consultation with the Secretaries of Agriculture, Interior, Defense, and the heads of such other agencies as the Administrator may determine, to develop procedures necessary to facilitate appropriate access to Federal property for the siting of mobile services antennas.

The procedures should be developed in accordance with the following:

1. (a) Upon request, and to the extent permitted by law and where practicable, executive departments and agencies shall make available Federal Government buildings and lands for the siting of mobile service antennas. This should be done in accordance with Federal, State, and local laws and regulations, and consistent with national security concerns (including minimizing mutual electromagnetic interactions), public health and safety concerns, environmental and aesthetic concerns, preservation of historic buildings and monuments, protection of natural and cultural resources, protection of national park and wilderness values, protection of National Wildlife Refuge systems, and subject to any Federal requirements promulgated by the agency managing the facility and the Federal Communications Commission, the Federal Aviation Administration, National Telecommunications and Information Administration, and other relevant departments and agencies.

(b) Antennas on Federal buildings or land may not contain any advertising.

(c) Federal property does not include lands held by the United States in trust for individual or Native American tribal governments.

(d) Agencies shall retain discretion to reject inappropriate siting requests, and assure adequate protection of public property and timely removal of equipment and structures at the end of service.

2. All procedures and mechanisms adopted regarding access to Federal property shall be clear and simple so as to facilitate the efficient and rapid buildout of the national wireless communications infrastructure.

3. Unless otherwise prohibited by or inconsistent with Federal law, agencies shall charge fees based on market value for siting antennas on Federal

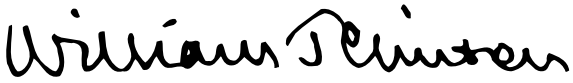
property, and may use competitive procedures if not all applicants can be accommodated.

This memorandum does not give the siting of mobile services antennas priority over other authorized uses of Federal buildings or land.

All independent regulatory commissions and agencies are requested to comply with the provisions of this memorandum.

This memorandum is not intended to create any right, benefit or trust responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers, or any other person.

This memorandum shall be published in the **Federal Register**.



THE WHITE HOUSE,
Washington, August 10, 1995.

[FR Doc. 95–20214
Filed 8–10–95; 4:15 pm]
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An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

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1–39, Vol. I		15.00	[2] July 1, 1984
1–39, Vol. II		19.00	[2] July 1, 1984
1–39, Vol. III		18.00	[2] July 1, 1984
1–190	(869–022–00121–3)	31.00	July 1, 1994
191–399	(869–022–00122–1)	36.00	July 1, 1994
400–629	(869–022–00123–0)	26.00	July 1, 1994
630–699	(869–026–00127–8)	14.00	[5] July 1, 1991
700–799	(869–022–00125–6)	21.00	July 1, 1994
800–End	(869–022–00126–4)	22.00	July 1, 1994
33 Parts:			
1–124	(869–022–00127–2)	20.00	July 1, 1994
125–199	(869–022–00128–1)	26.00	July 1, 1994
200–End	(869–022–00129–9)	24.00	July 1, 1994
34 Parts:			
1–299	(869–022–00130–2)	28.00	July 1, 1994
300–399	(869–022–00131–1)	21.00	July 1, 1994
400–End	(869–022–00132–9)	40.00	July 1, 1994
35	(869–022–00133–7)	12.00	July 1, 1994
36 Parts:			
1–199	(869–022–00134–5)	15.00	July 1, 1994
200–End	(869–022–00135–3)	37.00	July 1, 1994
37	(869–022–00136–1)	20.00	July 1, 1994
38 Parts:			
0–17	(869–022–00137–0)	30.00	July 1, 1994
18–End	(869–022–00138–8)	29.00	July 1, 1994
39	(869–022–00139–6)	16.00	July 1, 1994
40 Parts:			
1–51	(869–022–00140–0)	39.00	July 1, 1994
52	(869–022–00141–8)	39.00	July 1, 1994
53–59	(869–022–00142–6)	11.00	July 1, 1994
60	(869-022-00143-4)	36.00	July 1, 1994
61–80	(869–022–00144–2)	41.00	July 1, 1994
81–85	(869–022–00145–1)	23.00	July 1, 1994
86–99	(869–022–00146–9)	41.00	July 1, 1994
100–149	(869–022–00147–7)	39.00	July 1, 1994
150–189	(869–022–00148–5)	24.00	July 1, 1994
190–259	(869–022–00149–3)	18.00	July 1, 1994
260–299	(869–022–00150–7)	36.00	July 1, 1994
300–399	(869–022–00151–5)	18.00	July 1, 1994
400–424	(869–022–00152–3)	27.00	July 1, 1994
425–699	(869–022–00153–1)	30.00	July 1, 1994
700–789	(869–022–00154–0)	28.00	July 1, 1994
790–End	(869–022–00155–8)	27.00	July 1, 1994
41 Chapters:			
1, 1–1 to 1–10		13.00	[3] July 1, 1984
1, 1–11 to Appendix, 2 (2 Reserved)		13.00	[3] July 1, 1984
3–6		14.00	[3] July 1, 1984
7		6.00	[3] July 1, 1984
8		4.50	[3] July 1, 1984
9		13.00	[3] July 1, 1984
10–17		9.50	[3] July 1, 1984
18, Vol. I, Parts 1–5		13.00	[3] July 1, 1984
18, Vol. II, Parts 6–19		13.00	[3] July 1, 1984
18, Vol. III, Parts 20–52		13.00	[3] July 1, 1984
19–100		13.00	[3] July 1, 1984
1–100	(869–022–00156–6)	9.50	July 1, 1994
101	(869–022–00157–4)	29.00	July 1, 1994
102–200	(869–022–00158–2)	15.00	July 1, 1994
201–End	(869–022–00159–1)	13.00	July 1, 1994
42 Parts:			
1–399	(869–022–00160–4)	24.00	Oct. 1, 1994
400–429	(869–022–00161–2)	26.00	Oct. 1, 1994
430–End	(869–022–00162–1)	36.00	Oct. 1, 1994
43 Parts:			
1–999	(869–022–00163–9)	23.00	Oct. 1, 1994
1000–3999	(869–022–00164–7)	31.00	Oct. 1, 1994
4000–End	(869–022–00165–5)	14.00	Oct. 1, 1994
44	(869–022–00166–3)	27.00	Oct. 1, 1994
45 Parts:			
1–199	(869–022–00167–1)	22.00	Oct. 1, 1994
200–499	(869–022–00168–0)	15.00	Oct. 1, 1994
500–1199	(869–022–00169–8)	32.00	Oct. 1, 1994
1200–End	(869–022–00170–1)	26.00	Oct. 1, 1994
46 Parts:			
1–40	(869–022–00171–0)	20.00	Oct. 1, 1994
41–69	(869–022–00172–8)	16.00	Oct. 1, 1994
70–89	(869–022–00173–6)	8.50	Oct. 1, 1994
90–139	(869–022–00174–4)	15.00	Oct. 1, 1994
140–155	(869–022–00175–2)	12.00	Oct. 1, 1994
156–165	(869–022–00176–1)	17.00	[7] Oct. 1, 1993
166–199	(869–022–00177–9)	17.00	Oct. 1, 1994
200–499	(869–022–00178–7)	21.00	Oct. 1, 1994
500–End	(869–022–00179–5)	15.00	Oct. 1, 1994
47 Parts:			
0–19	(869–022–00180–9)	25.00	Oct. 1, 1994
20–39	(869–022–00181–7)	20.00	Oct. 1, 1994
40–69	(869–022–00182–5)	14.00	Oct. 1, 1994
70–79	(869–022–00183–3)	24.00	Oct. 1, 1994
80–End	(869–022–00184–1)	26.00	Oct. 1, 1994
48 Chapters:			
1 (Parts 1–51)	(869–022–00185–0)	36.00	Oct. 1, 1994
1 (Parts 52–99)	(869–022–00186–8)	23.00	Oct. 1, 1994
2 (Parts 201–251)	(869–022–00187–6)	16.00	Oct. 1, 1994
2 (Parts 252–299)	(869–022–00188–4)	13.00	Oct. 1, 1994
3–6	(869–022–00189–2)	23.00	Oct. 1, 1994
7–14	(869–022–00190–6)	30.00	Oct. 1, 1994
15–28	(869–022–00191–4)	32.00	Oct. 1, 1994
29–End	(869–022–00192–2)	17.00	Oct. 1, 1994
49 Parts:			
1–99	(869–022–00193–1)	24.00	Oct. 1, 1994
100–177	(869–022–00194–9)	30.00	Oct. 1, 1994
178–199	(869–022–00195–7)	21.00	Oct. 1, 1994
200–399	(869–022–00196–5)	30.00	Oct. 1, 1994
400–999	(869–022–00197–3)	35.00	Oct. 1, 1994
1000–1199	(869–022–00198–1)	19.00	Oct. 1, 1994
1200–End	(869–022–00199–0)	15.00	Oct. 1, 1994
50 Parts:			
1–199	(869–022–00200–7)	25.00	Oct. 1, 1994
200–599	(869–022–00201–5)	22.00	Oct. 1, 1994
600–End	(869–022–00202–3)	27.00	Oct. 1, 1994

Title	Stock Number	Price	Revision Date
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[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period Apr. 1, 1990 to Mar. 31, 1995. The CFR volume issued April 1, 1990, should be retained.

[5] No amendments to this volume were promulgated during the period July 1, 1991 to June 30, 1995. The CFR volume issued July 1, 1991, should be retained.

[6] No amendments to this volume were promulgated during the period January 1, 1993 to December 31, 1994. The CFR volume issued January 1, 1993, should be retained.

[7] No amendments to this volume were promulgated during the period October 1, 1993, to September 30, 1994. The CFR volume issued October 1, 1993, should be retained.

[8] No amendments to this volume were promulgated during the period April 1, 1994 to March 31, 1995. The CFR volume issued April 1, 1994, should be retained.

[9] Note: Title 19, CFR Parts 141-199, revised 4-1-95 volume is being republished to restore inadvertently omitted text.