

to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that under section 2.B.2 of Commandant Instruction M16475.1B, this rule is categorically excluded from further environmental documentation. A Categorical Exclusion Determination statement is available in the docket for inspection or copying where indicated under "ADDRESSES."

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

For the reasons set out in the preamble, the Coast Guard is amending 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REQUIREMENTS

Subpart B—Specific Requirements

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; and 33 CFR 1.05-1(g).

2. Section 117.185 is temporarily revised to read as follows:

§ 117.185 Pacheco Creek

During the period June 1, 1993 to September 30, 1993, the draw of the Contra Costa Highway Bridge, mile 1.0, and the Southern Pacific Railroad Bridge, mile 1.1, both near Martinez, need not open for the passage of vessels.

Dated: May 21, 1993.

M. E. Gilbert,

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

[FR Doc. 93-14066 Filed 6-16-93; 8:45 am]

BILLING CODE 4910-14-M

33 CFR Part 117

[CGD 11-92-10]

Drawbridge Operation Regulations; Mokelumne River, Sacramento County, CA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: At the request of the California Department of Transportation (CALTRANS), the Coast Guard is revising the regulations governing the Mokelumne River Bridge near Isleton, California. This change is being made because of serious highway traffic congestion during periods of peak highway and waterway use. This action

will reduce highway congestion and will still provide for the reasonable needs of navigation.

EFFECTIVE DATE: This rule becomes effective on July 19, 1993.

FOR FURTHER INFORMATION CONTACT: Susan Worden, Bridge Section, Aids to Navigation and Waterways Management Branch, Eleventh Coast Guard District at (510) 437-3514.

SUPPLEMENTARY INFORMATION:

Drafting Information:

The drafters of this rule are Susan Worden, project manager, and Lieutenant Commander Craig M. Juckniess, project counsel, Eleventh Coast Guard District Legal Office.

Background and Purpose:

Highway 12 is the major east-west arterial in the Sacramento-San Joaquin River Delta. Traffic has been increasing on the roadway for many years and, in some locations near the Mokelumne River Bridge, peak traffic volumes exceed 1,000 vehicles per hour. The highway crosses three major recreational waterways on drawbridges, and peak highway periods often coincide with peak waterway use periods. Traffic backups on this two lane road are sometimes 8 miles long, and drawbridge openings exacerbate the highway traffic congestion. The Mokelumne River Bridge provides only 7 feet vertical clearance when closed and must open for most of the vessels using the waterway. Prior to the tests of this regulation, the bridge was sometimes open for vessels more than 30 minutes each hour. The revised regulation will limit openings for recreational vessels to three times an hour during peak highway traffic periods on summer weekends and holidays. Openings for commercial vessels are infrequent on weekends and holidays, and it is not safe for commercial vessels to maneuver or stop in the channel. Accordingly, commercial vessels are excluded from the regulation and will be provided openings upon signal.

Regulatory History

On February 8, 1993 the Coast Guard published a Notice of Proposed Rulemaking in the Federal Register (58 FR 7499) concerning this proposal. The Commander, Eleventh Coast Guard District also published the proposal as a Public Notice 11-65d dated February 16, 1993. In each notice interested persons were given until March 25, 1993 to submit comments.

As early as 1988, regulations similar to the permanent regulation were tested

to determine whether vessels could safely wait for openings spaced 20 minutes apart. In 1990, a temporary regulation was enacted for the summer boating period 1 May-31 October. The regulations was published in the Federal Register on June 7, 1990 (55 FR 23202) and in the local area, by a Public Notice. Comments were solicited during the period the regulations was in effect. In 1991, another similar regulation was published in the Federal Register on May 8, 1991 (56 FR 21301) and in the local area, by a Public Notice. Comments were solicited during the period the regulation was in effect. In 1992, another similar regulation was published in the Federal Register on April 22, 1992 (57 FR 14644) and in the local area, by a Public Notice. Again comments were solicited during the period the regulation was in effect.

Discussion of comments

As discussed in the NPRM, during the 1988 test and the 1990-1992 temporary regulation implementations, the Coast Guard received seven comments—four in support and three in opposition. During the most recent advertisement, three comments were received, all supporting the regulation. The commenters opposing the regulation expressed concern for vessels waiting for openings and vessels using a fuel dock near the bridge, and asked for a 15 minute opening interval instead of a 20 minute interval. The Coast Guard observed bridge operations under the new regulation and concluded that there is adequate room in the channel for pleasure vessels to await bridge openings and maneuver safely. The adjacent levees shelter waiting vessels from strong winds. The regulation had no noticeable effect on vessels using a nearby fuel dock. The opening interval appears to be a reasonable compromise between highway and waterway traffic.

Economic Assessment and Certification

This regulation is considered to be non-major under Executive Order 12291 on Federal Regulation and nonsignificant under Department of Transportation regulatory policies and procedures (44 FR 11034, February 26, 1979). The economic impact of this rule is expected to be so minimal that a full regulatory evaluation is unnecessary. Vehicular traffic flow will be enhanced and no vessels will be prevented from using the waterway. Since the economic impact of this rule is expected to be minimal, the Coast Guard certifies that, if adopted, it will not have a significant impact on a substantial number of small entities.

Paperwork Reduction Act

This rule contains no collection of information or recordkeeping requirements under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

Federalism

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

Environment

This rulemaking has been thoroughly reviewed by the Coast Guard and it has been determined to be categorically excluded from further environmental documentation in accordance with section 2.B.2.g.(5) of Commandant Instruction M16475.1B. A Categorical Exclusion Determination statement has been prepared and placed in the rulemaking docket.

List of Subjects in 33 CFR Part 117

Bridges.

In consideration of the foregoing, part 117 of title 33 of the Code of Federal Regulations is amended as follows:

PART 117—DRAWBRIDGE OPERATION REQUIREMENTS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46 and 33 CFR 1.05-1(g).

Subpart B—Specific Requirements

2. Section 117.175 is amended by revising paragraph (a) to read as follows:

§ 117.175 Mokelumne River.

(a) The draw of the California Department of Transportation highway bridge, the Mokelumne River Bridge, mile 3.0, at East Isleton shall open upon signal as follows:

(1) From November 1 through April 30 from 9 a.m. to 5 p.m.

(2) From May 1 through October 31 from 6 a.m. to 10 p.m., except that during the following periods the draw need only open for recreational vessels on the hour, 20 minutes past the hour, and 40 minutes past the hour:

Saturdays 10 a.m. until 2 p.m.

Sundays 11 a.m. until 6 p.m.

Memorial Day; 4th of July; and Labor Day 11 a.m. until 6 p.m.

(3) At all other times the draw shall open on signal if at least 4 hours notice is given to the drawtender at Rio Vista bridge over the Sacramento River, mile 12.8.

(4) Emergency vessels of the United States, state or commercial vessels engaged in rescue or emergency salvage operations, and vessels in distress shall be passed as soon as possible but no later than one hour after notice is given.

* * * * *

Date: May 21, 1993.

M.E. Gilbert,

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

[FR Doc. 93-14068 Filed 6-16-93; 8:45 am]

BILLING CODE 4910-14-M

33 CFR Part 165

[COTP Baltimore, MD Regulation 93-05-02]

Safety Zone Regulation; Hammerman Area of Gunpowder Falls State Park, Baltimore County, MD

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the purpose of the Maryland "Swim For Life", at the request of the Maryland "Swim For Life" Committee of Baltimore, MD. The "Swim For Life" event will consist of a two and a one half mile swim from the Hammerman area beach number five, to the Maxwell Point buoy, thence to Oliver Point buoy and thence to Hammerman area beach numbers one and two. The safety zone is necessary to control small craft and recreational vessel traffic, and to provide for the safety of life and property on U.S. navigable waters from the hazards associated with this swimming event. Entry into this zone is prohibited unless authorized by the Captain of the Port.

EFFECTIVE DATE: This regulation will become effective at 7 a.m. June 19, 1993, and terminate at 1 p.m. June 19, 1993, unless sooner terminated by Captain of the Port, Baltimore, Maryland. The alternate event date will be June 20, 1993, encompassing the same area description and running from 7 a.m. to 1 p.m., unless sooner terminated by the Captain of the Port, Baltimore, Maryland.

FOR FURTHER INFORMATION CONTACT: Lieutenant Junior Grade Mark Williams at U.S. Coast Guard Marine Safety Office Baltimore, 40 S. Gay Street, Baltimore, Maryland, (410) 962-5100.

SUPPLEMENTARY INFORMATION: As allowed by 5 U.S.C. 553(b), the Coast Guard has not published a notice of proposed rulemaking on this regulation because it would be contrary to the public interest to cancel the event or to hold the event without appropriate

regulatory safeguards for the participants.

Drafting Information

The drafters of this regulation are Lieutenant Junior Grade Mark R. Williams, project officer for the Captain of the Port, Baltimore, Maryland and Lieutenant Commander Keith B. Letourneau, project attorney, Fifth Coast Guard District Legal Staff.

Background and Purpose

The Maryland "Swim For Life" Committee filed an application with the U.S. Coast Guard, Group Baltimore requesting a safety zone for the Maryland "Swim For Life" event, to take place on June 19, 1993. The alternate event date will be June 20, 1993, encompassing the same area description and time frame. As part of their application, the Maryland "Swim For Life" Committee requested the Coast Guard provide control of spectator and commercial traffic during the swimming event.

Discussion of Regulations

The event will start at the Gunpowder Falls State Park, Baltimore County Maryland, Hammerman area beach number five, and proceed southeast to the Maxwell Point buoy, thence north to the Oliver Point buoy, and return southwest to the Hammerman beach areas one and two, at Gunpowder Falls State Park. This safety zone will encompass all waters 500 yards on either side of lines drawn from a point at Hammerman area beach number five, located at latitude 39° 21.8' N., longitude 76° 20.4' W., to the Maxwell Point buoy, located at latitude 39° 21.6' N., longitude 76° 19.9' W., thence north to the Oliver Point buoy, located at latitude 39° 22.6' N., longitude 76° 20.2' W., and finally south to a point at the Hammerman area beach numbers one and two at latitude 39° 21.8' N., longitude 76° 20.4' W. This regulation is necessary to ensure the safety of spectator craft, recreational vessels as well as swimmers participating in the event, and to provide for the safety of life and property on U.S. navigable waters during the event. Since the Gunpowder Falls river will not be closed for an extended period, vessel traffic should not be severely disrupted.

Economic Assessment and Certification

This proposed regulation is considered to be non-major under Executive Order 12291 on Federal Regulation and nonsignificant under Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979). The economic

impact of this proposal is expected to be so minimal that a full regulatory evaluation is unnecessary.

The Coast Guard also considered the impact of this regulation on small entities and concluded that such impact is expected to be minimal. Therefore the Coast Guard certifies under 5 U.S.C. 605(b), that this regulation will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

Temporary Regulations

In consideration of the foregoing, the Coast Guard is amending part 165 of title 33, Code of Federal Regulations as follows:

PART 165—[AMENDED]

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05-(g), 6.04-1, 6.04-6, and 160.5; 49 CFR 1.46.

2. A temporary section 165.T5102 is added to read as follows:

§ 165.T5102 Safety Zone: Hammerman Area of the Gunpowder Falls State Park, Gunpowder State Park, MD.

(a) *Location.* The following area is a safety zone. All waters 500 yards either side of a line connecting the following points beginning at

Latitude	Longitude
39°21.6' N.	76° 20.4' W., thence to
39°21.6' N.	76° 19.9' W., thence to
39°22.6' N.	76° 20.2' W., thence to
39°21.6' N.	76° 20.4' W.

(b) *Designated COTP representative.* The designated representative of the Captain of the Port is any Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port, Baltimore, Maryland to act on his behalf. The following officers are designated by the Captain of the Port: the Coast Guard Patrol Commander, the senior boarding officer on each vessel enforcing the safety zone, and the Duty Officer at the Marine Safety Office Baltimore, Maryland.

(c) *Local Regulations.* Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area.

(1) The operator of any vessel in this safety zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant, or petty officer on board a vessel displaying a Coast Guard Ensign.

(ii) Proceed as directed by any commissioned, warrant, or petty officer on board a vessel displaying a Coast Guard Ensign.

(2) The Captain of the Port and the Duty Officer at the Marine Safety Office, Baltimore, Maryland can be contacted at telephone number (410) 962-5100.

(3) The Coast Guard Patrol Commander and the senior boarding officer on each vessel enforcing the safety zone can be contacted on VHF-FM channels 16 and 81.

(4) Any spectator vessel may anchor outside of the regulated areas specified in paragraph (2)(a) of these regulations, but may not block a navigable channel.

(d) *Effective dates:* This regulation is effective from 7 a.m. June 19, 1993, to 1 p.m. June 19, 1993; the alternate day will be June 20, 1993, encompassing the same area description and time frame; unless sooner terminated by the Captain of the Port, Baltimore, Maryland.

Dated: May 25, 1993.

R.L. Edmiston,

Captain, U.S. Coast Guard, Captain of the Port, Baltimore, Maryland.

[FR Doc. 93-14074 Filed 6-16-93; 8:45 am]

BILLING CODE 4910-14-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IN03-2-5848; FRL-4667-3]

Approval and Promulgation of Implementation Plans; Indiana

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Final rule.

SUMMARY: USEPA is disapproving a State submittal of a revision to the Indiana State Implementation Plan (SIP) for ozone. On April 10, 1989, the Indiana Department of Environmental Management (IDEM) submitted a new rule, that applies to only one source, Jeffboat, Incorporated (Jeffboat), located in Clark County, Indiana, which is designated non-attainment for ozone. This rule was developed in response to a May 26, 1988, SIP call issued under the Clean Air Act (Act).

DATES: This final rulemaking becomes effective on July 19, 1993.

ADDRESSES: Copies of the SIP revision request and other materials relating to this rulemaking are available for inspection at the following address: (It is recommended that you telephone Randolph O. Cano, at (312) 886-6036, before visiting the Region 5 office.) U.S. Environmental Protection Agency,

Region 5, Regulation Development Branch, 77 West Jackson, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Randolph O. Cano, Regulation Development Branch (5AR-18J), U.S. Environmental Protection Agency, 77 West Jackson, Chicago, Illinois 60604.

SUPPLEMENTARY INFORMATION: On February 24, 1993 (58 FR 11200), USEPA published a proposed rule on this requested SIP revision, as summarized below. For a detailed explanation, the proposed rule should be consulted.

Section 172 of the Act, as amended in 1977, requires that an approvable SIP include legally enforceable requirements reflecting the application of reasonably available control technology (RACT) for stationary sources of volatile organic compounds (VOC) emissions. In partial response to the requirement for RACT VOC rules, Indiana submitted rules covering many of the applicable sources in the Indiana ozone nonattainment areas. Some source categories, however, were not covered by these rules. Because the State failed to adopt and submit to USEPA RACT level emission controls for all the required source categories, including marine vessel surface coating, section 110(a)(2)(H) of the Act required a SIP call.

On May 26, 1988, USEPA issued a SIP call, notifying the Governor of Indiana, pursuant to section 110(a)(2)(H) of the Act, that the Indiana SIP for ozone was substantially inadequate to attain the NAAQS. On June 17, 1988, USEPA sent a letter detailing the SIP inadequacies, including the absence of a marine vessel surface coating rule.

On November 15, 1990, Congress enacted the Clean Air Act Amendments of 1990. Public Law 101-549, 104 Stat. 2399, codified at 42 U.S.C. 7401-7617q. Under section 182(a)(2)(A) of the 1990 Amendments, areas designated nonattainment before enactment of the 1990 Amendments and which retained that designation and were classified as "marginal" or above as of enactment are required to correct previously identified deficiencies. Under section 182(a)(2)(A), those areas are required by May 15, 1991, to correct deficiencies in the plan concerning RACT which was required under section 172(b) of the 1977 amendments, as that requirement was interpreted in pre-amended guidance. The SIP call letters interpreted that guidance and indicated corrections necessary for specific nonattainment areas. The ozone nonattainment area encompassing Clark County, Indiana is classified as "moderate" and is

therefore, subject to the RACT correction requirement. Indiana's SIP revision request which it submitted in response to the SIP call letter, also responds to part of the RACT correction requirement.

On April 10, 1989, the IDEM submitted a new rule, Title 326 of the Indiana Administrative Code (326 IAC) 8-2-13, Marine Vessel Surface Coating. This new rule applies to only one source, Jeffboat, located in Clark County, Indiana which is designated nonattainment for ozone and classified as a moderate nonattainment area. 326 IAC 8-2-13 was developed in response to USEPA's May 26, 1988, SIP call letter.

USEPA proposed to disapprove the requested SIP revision on February 24, 1993, (see 58 FR 11200) because of the State's failure to demonstrate that the rule represents RACT for Jeffboat. The public comment period on the proposed rule closed on April 26, 1993. No comments were received in response to USEPA's solicitation of comments on the requested SIP revision and the proposed rulemaking action.

Final Rulemaking Action

USEPA is disapproving this rule, Marine Vessel Surface Coating (326 IAC 8-2-13), because the State has not adequately demonstrated that the rule represents RACT for Jeffboat. Therefore, the rule does not meet the requirement under section 182(a)(2)(A) of the Act that Indiana correct that rule so that it meets the RACT requirement of section 172 of the Act as amended in 1977. This action becomes effective July 19, 1993.

This action has been classified as a Table 3 action by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214-2225). On January 6, 1989, the Office of Management and Budget (OMB) waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of Section 3 of Executive Order 12291 for a period of 2 years. USEPA has submitted a request for a permanent waiver for Table 2 and 3 SIP revisions. OMB has agreed to continue the temporary waiver until such time as it rules on USEPA's request.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, USEPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, USEPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government

entities with jurisdiction over populations of less than 50,000.

This disapproval affects only one source, Jeffboat. Therefore, it does not have a significant impact on a substantial number of small entities. The request does not meet the requirements of the CAA and USEPA cannot approve the request. Therefore, USEPA has no option but to disapprove the submittal.

Under Executive Order 12291, today's action is not "Major".

List of Subjects in 40 CFR Part 52

Air pollution control, Hydrocarbons, Intergovernmental relations, Ozone, Volatile organic compounds.

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

Dated: June 3, 1993.

Valdas V. Adamkus,
Regional Administrator.

[FR Doc. 93-14252 Filed 6-16-93; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Part 279

[FRL-4667-8]

Identification and Listing of Hazardous Waste; Recycled Used Oil Management Standards; Correction

AGENCY: Environmental Protection Agency.

ACTION: Final rule; correction.

SUMMARY: The Environmental Protection Agency (EPA) is correcting errors in the hazardous waste regulations that appeared in the Federal Register on May 3, 1993 (58 FR 26420). In that document, EPA published corrections to the used oil management standards that were originally promulgated on September 10, 1992 (57 FR 41566). In the May 3 notice, EPA inadvertently amended several sections of part 279 dealing with notification requirements for used oil handlers. This action corrects this error and restores the original language from the September 10, 1992 final rule. In addition, EPA inadvertently omitted the explanation for a correction in the May 3 notice. This action corrects this error.

EFFECTIVE DATE: June 17, 1993.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA/ Superfund Hotline at (800) 424-9346 (toll-free) or (703) 920-9810 in the Washington, DC metropolitan area. For specific information concerning the used oil management standards rulemaking, contact Ms. Eydie Pines at (202) 260-3509 or Bryan Groce at (202) 260-9550, Office of Solid Waste, U.S.

EPA, 401 M Street, SW., Washington, DC, 20460.

SUPPLEMENTARY INFORMATION:

I. Reason for This Document

The Agency promulgated management standards for recycled used oils on September 10, 1992 (57 FR 41566) and published a subsequent correction notice on May 3, 1993 (58 FR 26420). In the correction notice, EPA inadvertently amended four regulatory sections of Part 279 dealing with notification requirements for certain used oil handlers. Specifically, the correction notice revised paragraph (a) of §§ 279.42, 279.51, 279.62, and 279.73. These amendments were mistakenly included in the correction notice; the Agency did not intend to change these provisions. Therefore, today's notice corrects these four sections and restores the original language contained in the September 10 final rule.

In the May 3 notice, EPA also inadvertently omitted the explanation for one of the corrections clarifying the applicability of the part 279 regulations to on-specification used oil. This correction included the removal of the last sentence of § 279.72 (a). This sentence, originally placed in subpart H, Standards for Used Oil Marketers, establishes that on-specification used oil "that is to be burned for energy recovery is not subject to the requirements of this part." EPA was concerned that this provision might be unclear in light of the more complete explanation of the applicability of these regulations to on-specification used oil found in § 279.11. The final sentence of § 279.11 reads as follows: "Once the used oil that is to be burned for energy recovery has been shown not to exceed any specification and the person making that showing complies with §§ 279.72, 279.73, and 279.74(b), the used oil is no longer subject to this part." EPA therefore removed the sentence in § 279.72(a) to avoid any confusion about the applicability of the Part 279 regulations to on-specification used oil.

II. Administrative Procedures Act Requirements

This action does not create any new regulatory requirements; rather, it reinstates existing language that was inadvertently changed by the Agency in a correction notice and restores an inadvertently omitted explanation. For this reason, EPA finds that good cause exists under section 3010(b)(3) of RCRA (42 U.S.C. 6930(b)(3)) and under 5 U.S.C. 553(d) to provide for an immediate effective date. EPA also believes good cause exists to waive the

notice and comment requirements of the APA. As this rule merely corrects errors in a previous final rule, notice and comment are unnecessary.

III. Regulatory Impact Analysis

Under Executive Order 12291, EPA must judge whether a regulation is "major" and, therefore, subject to the requirement of a Regulatory Impact Analysis (RIA). Due to the nature of this regulation (correction notice), the amendment is not "major;" therefore, no RIA is required.

List of Subjects in 40 CFR Part 279

Petroleum, Recycling, Reporting and recordkeeping requirements, Used oil.

Dated: May 28, 1993.

Richard J. Guimond,
Assistant Surgeon General, USPHS Acting
Assistant Administrator.

The following corrections are made to the rules in, Identification and Listing of Hazardous Waste; Recycled Used Oil Management Standards; Corrections, published in the Federal Register on May 3, 1993 (58 FR 26420).

PART 279—STANDARDS FOR THE MANAGEMENT OF USED OIL

1. The authority citation for part 279 continues to read as follows:

Authority: Sections 1006, 2002(a), 3001 through 3007, 3010, 3014, and 7004 of the Solid Waste Disposal Act, as amended (42 U.S.C. 6905, 6912(a), 6921 through 6927, 6930, 6934, and 6974); and sections 101(37) and 114(c) of CERCLA (42 U.S.C. 9601(37) and 9614(c)).

2. Paragraph (a) of § 279.42 is revised to read as follows:

§ 279.42 Notification.

(a) *Identification numbers.* Used oil transporters who have not previously complied with the notification requirements of RCRA section 3010 must comply with these requirements and obtain an EPA identification number.

3. Paragraph (a) of § 279.51 is revised to read as follows:

§ 279.51 Notification.

(a) *Identification numbers.* Used oil processors and re-refiners who have not previously complied with the notification requirements of RCRA section 3010 must comply with these requirements and obtain an EPA identification number.

4. Paragraph (a) of § 279.62 is revised to read as follows:

§ 279.62 Notification.

(a) *Identification numbers.* Used oil burners which have not previously complied with the notification requirements of RCRA section 3010 must comply with these requirements and obtain an EPA identification number.

5. Paragraph (a) of § 279.73 is revised to read as follows:

§ 279.73 Notification.

(a) *Identification numbers.* A used oil fuel marketer subject to the requirements of this subpart who has not previously complied with the notification requirements of RCRA section 3010 must comply with these requirements and obtain an EPA identification number.

[FR Doc. 93-14316 Filed 6-16-93; 8:45 am]

BILLING CODE 5550-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 50

Sterilization of Persons in Federally Assisted Family Planning Projects

AGENCY: Public Health Service, HHS.

ACTION: Final rule.

SUMMARY: This final rule amends Public Health Service regulations, which govern the sterilization of persons in federally assisted family planning projects, by removing informational material concerning sterilizations contained in the appendix relating to "Required Consent Form." The Department had previously made this information generally available in the form of pamphlets, but it has recently updated the pamphlets, as much of the information has become obsolete, and it is no longer distributing the obsolete versions of the pamphlets.

EFFECTIVE DATE: This rule is effective June 17, 1993.

FOR FURTHER INFORMATION CONTACT: Samuel S. Taylor, Acting Director, Office of Family Planning, Office of Population Affairs, Office of the Assistant Secretary for Health, Hubert H. Humphrey Building, room 736-E, 200 Independence Avenue, SW., Washington, DC 20201; telephone: (202) 690-8151.

SUPPLEMENTARY INFORMATION: On November 8, 1978, this Department published in the Federal Register (43 FR 52146), final rules prescribing the

requirements for sterilizations funded under the various health programs administered by the Department. Included with the portion of the rules pertaining to those programs administered by the Public Health Service (PHS), as part of the appendix to subpart B, was a copy of two pamphlets—one for women, one for men—explaining the sterilization procedure and its risks and benefits. The pamphlets are not part of the regulation and the removal of the text of the pamphlets does not effect the requirements and restrictions of the regulations. As the preamble to the rules explained, the pamphlets were published with the rules for informational purposes only.

Many of the particular facts that comments suggested be required will generally be conveyed in the discussion of discomforts and risks. Requiring that a specific pamphlet be used would be analogous, so this suggestion has likewise been rejected. However, while the Department is not inclined to mandate use of an informational pamphlet, it is strongly of the view that provision of a pamphlet is an efficient and effective means of reinforcing the information required to be given orally. It also gives the individual to be sterilized information to consider during the waiting period. Consequently, it has developed pamphlets setting out the general information required under § 50.204(a) for male and female surgical sterilizations. The Department plans to make these pamphlets generally available for use by providers and encourages their use. These pamphlets are published following the rules below.

43 FR 52159. However, the pamphlets have continued to appear with the codification of the PHS rules from 1978 to the present; they do not appear with the codification of the companion Health Care Financing Administration (HCFA) rules at 42 CFR part 441, subpart F.

Numerous advances in information about sterilization procedures and the effectiveness of other forms of family planning, as well as the development of new family planning technologies, have made much of the information contained in the 1978 pamphlets obsolete or inaccurate. Consequently, the PHS has revised both pamphlets to incorporate current information and to clarify them and is making the revised pamphlets available to the public. (Copies of the revised pamphlets may be obtained by writing the Family Life Information Exchange, P.O. Box 37298, Washington, DC 20013-7299, or by calling 301-585-6636.) Further, the Department will no longer distribute the outdated version set out in the appendix to subpart B of part 50. This results in an anomalous situation in which the

version in the "Code of Federal Regulations," which purports to be the official version of the pamphlets, is in fact both outdated and no longer generally available.

The Department has concluded that this situation should be corrected. In order to effect a change in the material codified in the "Code of Federal Regulations," however, the Department must issue this change in the form of a final rule, even though the material being removed is informational only and not part of the existing regulations. Accordingly, this final rule amends 42 CFR part 50 by removing the obsolete pamphlet language contained in the appendix to subpart B—that portion of the appendix following the "Physician's Statement," beginning with the heading "Your Sterilization Operation: Information for Women" and the remainder of the appendix following this heading will be removed. This amendment will also make the codified PHS regulations more consistent with the companion HCFA regulations pertaining to sterilizations and eliminate any confusion that this discrepancy may have caused.

Justification for Omitting Notice of Proposed Rulemaking

Since this amendment is of a purely technical nature, and, in fact, does not alter or amend existing regulatory provisions, the Secretary has determined, pursuant to 5 U.S.C. 553 and departmental policy that it is unnecessary and impractical to follow proposed rulemaking procedures or to delay the effective date of this regulation.

Regulatory Flexibility Act and Executive Order 12291

This rule is merely a technical removal of supplemental out-of-date information. The rule will neither exceed the threshold level of \$100 million established in section 1(b) of Executive Order 12291 nor does it meet any of the additional criteria contained in the Executive Order. For these reasons, the Secretary has determined that this rule is not a major rule under Executive Order 12291 and a regulatory impact analysis is not required. Furthermore, in accordance with the requirements of the Regulatory Flexibility Act of 1980, the Secretary certifies that this regulation will not have a significant economic impact on a substantial number of small entities, and therefore, a regulatory flexibility analysis is not required.

Paperwork Reduction Act of 1980

This final rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980. 44 U.S.C. 3501 et seq.

List of Subjects in 42 CFR Part 50

Family planning—Birth control, Grant programs—Health, Health facilities.

Dated: March 18, 1993.

Audrey F. Manley,
Acting Assistant Secretary for Health.

Approved: May 5, 1993.

Donna E. Shalala,
Secretary.

Accordingly, in 42 CFR part 50, the appendix to subpart B, "Required Consent Form," is amended as set forth below:

PART 50—POLICIES OF GENERAL APPLICABILITY

1. The authority citation for 42 CFR part 50 continues to read as follows:

Authority: Sec. 215, Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); Sec. 1006, Public Health Service Act, 84 Stat. 1507 (42 U.S.C. 300a-4), unless otherwise noted.

Subpart B—Sterilization of Persons in Federally Assisted Family Planning Projects

2. The appendix to subpart B is amended by removing the centerhead "Your Sterilization Operation: Information for Women" and all text following it, and removing the centerhead "Your Sterilization Operation: Information for Men" and all text following it.

[FR Doc. 93-14155 Filed 6-16-93; 8:45 am]

BILLING CODE 4160-17-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 80

[PR Docket No. 92-164; FCC 93-219]

Class C Emergency Position Indicating Radio Beacons

AGENCY: Federal Communications Commission

ACTION: Final rule.

SUMMARY: This Report and Order amends the Commission's Rules to phase out the use of the Class C Emergency Position Indicating Radio Beacons (EPIRBs) after February 1, 1999. This action is in response to a request from the United States Coast Guard. Informing the maritime community now

that the Commission intends to eliminate authorization of Class C EPIRBs by February 1, 1999, will allow for amortization of existing Class C EPIRBs and provide sufficient time for the marine public to obtain another type of EPIRB prior to the full implementation of the Global Maritime Distress and Safety System.

EFFECTIVE DATE: July 19, 1993.

FOR FURTHER INFORMATION CONTACT:

George R. Dillon, Aviation and Marine Branch, Private Radio Bureau, Federal Communications Commission, 2025 M St. NW., Washington, DC 20554; or telephone (202) 632-7175.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, PR Docket No. 92-164, adopted May 3, 1993, and released May 18, 1993. The complete text of the Report and Order, including Appendices, is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street NW., Washington, DC. The full text also may be purchased from the Commission's copy contractor: International Transcription Services, 2100 M Street, NW., suite 140, Washington, DC 20037, (202) 857-3800.

Summary of Report and Order

1. The United States Coast Guard requested that the Commission amend its Maritime Services Rules (part 80) to eliminate authorization of Class C EPIRBs by February 1, 1999. EPIRBs are small, battery powered transmitters carried on ships for the purpose of sending a distress signal. Class C EPIRBs transmit distress signals on marine VHF channels 15 and 16 both as an alarm to alert others that a ship is in distress and as a beacon to aid in its location by search and rescue personnel. Because satellites do not monitor marine VHF channels 15 and 16, other nearby ships and coast stations can receive their distress signal.

2. The Global Maritime Distress and Safety System (GMDSS), which will be fully implemented by February 1, 1999, changes the mandatory watch requirement for ships from marine VHF channel 16 to an automated watch on Digital Selective Calling (DSC) channel 70. The Coast Guard also intends to discontinue its watch on marine VHF channel 16 after February 1, 1999. This lack of monitoring by satellites, ocean going vessels and the Coast Guard will dramatically reduce the effectiveness and need for Class C EPIRBs during search and rescue operations. Informing the maritime community now that the Commission intends to eliminate authorization of Class C EPIRBs by

February 1, 1999, will allow for amortization of existing Class C EPIRBs and provide sufficient time for the marine public to obtain another type of EPIRB prior to the full implementation of the GMDSS.

3. Accordingly, it is ordered that, Pursuant to the authority contained in sections 4(l) and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i) and 303(r), part 80 of the Commission's Rules, 47 CFR part 80, is amended as set forth below.

4. It is further ordered that, This Report and Order will be effective July 19, 1993.

List of Subjects in 47 CFR Part 80

Communications equipment, Marine safety, Radio

Federal Communications Commission.

Donna R. Searcy,
Secretary.

Final Rule

Part 80 of chapter I of title 47 of the Code of Federal Regulations is amended as follows:

PART 80—STATIONS IN THE MARITIME SERVICES

1. The authority citation for part 80 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303, unless otherwise noted. Interpret or apply 48 Stat. 1064–1068, 1081–1105, as amended; 47 U.S.C. 151–155, 301–609, 3 UST 3450, 3 UST 4726, 12 UST 2377.

2. Section 80.15 is amended by revising paragraph (e)(1) introductory text to read as follows:

§ 80.15 Eligibility for station license.

(e) EPIRB stations. (1) New class C EPIRB stations will not be authorized after February 1, 1995. Class C EPIRB stations installed and licensed before February 1, 1995, will be authorized until February 1, 1999:

3. Section 80.205 is amended by adding a new Footnote 13 to the "G3N" entry in the table in paragraph (a) to read as follows:

§ 80.205 Bandwidths.

(a) * * *

Class of emission	Emission designator	Authorized bandwidth (kHz)
-------------------	---------------------	----------------------------

G3N^{1,13} * * *

Class of emission	Emission designator	Authorized bandwidth (kHz)
-------------------	---------------------	----------------------------

* * *

⁹Applicable only to EPIRB's.

¹³ Class C EPIRB stations may not be used after February 1, 1999.

4. Section 80.207 is amended by adding a new Footnote 13 to the "156.750 and 156.800 MHz" entry in the table in paragraph (d) to read as follows:

§ 80.207 Classes of emission.

(d) * * *

Types of stations	Classes of emission
-------------------	---------------------

* * *

Distress, Urgency, and Safety^{8,9}

* * *

156.750 and 156.800 MHz¹³.

* * *

⁸ For direction finding equipment requirements see § 80.375.

⁹ Includes distress emissions used by ship, coast, EPIRB's and survival craft stations.

* * *

¹³ Class C EPIRB stations may not be used after February 1, 1999.

5. Section 80.209 is amended by adding a new Footnote 6 to the "Operating on 156.750 and 156.800 MHz" entry in the table in paragraph (a) to read as follows:

§ 80.209 Transmitter frequency tolerances.

(a) * * *

Frequency bands and categories of stations	Tolerances ¹
--	-------------------------

* * *

(5) * * *

(iv) Operating on 156.750 and 156.800 MHz⁶.

* * *

¹ Transmitters authorized prior to January 2, 1990, with frequency tolerances equal to or better than those required after this date will continue to be authorized in the maritime services provided they retain type acceptance and comply with the applicable standards in this part.

* * *

⁶ Class C EPIRB stations may not be used after February 1, 1999.

6. Section 80.1057 is amended by adding an introductory paragraph to read as follows:

§ 80.1057 Special requirements for Class C EPIRB stations.

Class C EPIRB's shall not be manufactured, imported, or sold in the United States after February 1, 1995. Class C EPIRB stations installed on board vessels before February 1, 1995, may be used until February 1, 1999, and not thereafter.

* * *

[FR Doc. 93-14244 Filed 6-16-93; 8:45 am]
BILLING CODE 6712-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 651

[Docket No. 930522-3122; I.D. #061493B]

Northeast Multispecies Fishery

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Amendment to emergency interim rule.

SUMMARY: The Secretary of Commerce (Secretary) amends the regulations implementing the Fishery Management Plan for the Northeast Multispecies Fishery (FMP). This amendment to the emergency rule published on June 8, 1993 (58 FR 32062) reopens to fishing the area designated as Closed Area II. The 2,500-pound (1,134-kg) haddock possession limit and ban on pair trawling in the Northeast multispecies fishery implemented by that rule remain in effect. The intended effect of this rule is to relieve some of the confusion and burden caused by the original implementation of the emergency interim rule while still providing additional protection to haddock and cod, and promoting the rebuilding of these depleted fish stocks.

EFFECTIVE DATES: This amendment to the emergency interim rule is effective June 14, 1993, through September 6, 1993.

FOR FURTHER INFORMATION CONTACT: Jack Terrill, Resource Policy Analyst (508-281-9252), Northeast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930.

SUPPLEMENTARY INFORMATION: On June 3, 1993, the Secretary implemented cod and haddock protection measures through an emergency interim rule published on June 8, 1993 (58 FR 32062). The rule implemented: A 2,500-pound (1,134-kg) haddock possession

limit applying to all vessels permitted under regulations for this fishery; the area known as Closed Area II was expanded by 20 minutes longitude to the west and 15 minutes latitude to the south along its existing western and southern boundaries; Closed Area II was closed through the month of June; and a ban on pair trawling in the multispecies fishery.

Regulations implementing the FMP (§ 651.21(a)) closed the area designated as Closed Area II from February 1 through May 31 of each year. On June 3, 1993, when the emergency interim rule became effective, vessels had already sailed and were fishing in the area to be re-opened under this rule. The area is approximately 120 miles (192.4 km) from shore and is fished primarily by larger vessels on trips lasting approximately 10 days.

On June 11, 1993, the Assistant Secretary of Commerce for Oceans and Atmosphere met with members of the fishing community from Maine, Massachusetts, and Rhode Island; local government officials from Gloucester, MA; Representative Peter Torkildsen; Congressional staff, a member of the Council, and the Council's Executive Director.

The representatives of the Council present stated that upon reviewing the Council's recommendation, it was not the Council's intention for the area to be extended in time but rather just expanded in area during the regulated closure months. They noted that the proposal being considered for Amendment 5 to the FMP would extend the area in time in the third year after implementation. The stated rationale for the delayed implementation was that it would allow Canada to implement a similar closure.

As a result of input from the fishing community and the confusion over what the recommendation from the Council was, the Secretary has determined that Closed Area II should be reopened immediately. The haddock possession limit of 2,500 pounds (1,134 kg) will remain in effect as well as the prohibition on the use of pair trawl gear in the Northeast multispecies fishery.

Classification

The Secretary has determined that this rule is necessary to respond to an emergency situation and is consistent with the Magnuson Act and with other applicable law.

The Secretary finds for good cause that the reasons justifying promulgation of this rule on an emergency basis also make it impracticable and contrary to the public interest to provide full notice and opportunity for public comment on

these emergency regulations, under the provisions of section 553(b) of the Administrative Procedure Act. Because this rule relieves a restriction, a 30-day delay of the effective date is not required under section 553(d)(1) of the Administrative Procedure Act. The Secretary notes, however, that substantial public comment was received and considered before deciding on this emergency action.

This emergency interim rule is exempt from the normal review procedures of E.O. 12291 as provided in section 8(a)(1) of that order. The rule is being reported to the Director of the Office of Management and Budget with an explanation of why it is not practicable to follow the regular procedures of that order.

This rule is exempt from the procedures of the Regulatory Flexibility Act because the rule is issued without opportunity for prior public comment.

This rule does not contain a collection-of-information requirement for the purposes of the Paperwork Reduction Act.

This rule will be implemented in a manner that is consistent, to the maximum extent practicable, with the approved coastal management programs of Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Pennsylvania, Delaware, Maryland, and Virginia. This rulemaking has been submitted for review by the responsible State agencies under section 307 of the Coastal Zone Management Act.

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

List of Subjects in 50 CFR Part 651

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: June 14, 1993.

Gary Matlock,

Acting Assistant Administrator for Fisheries,
National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 651 is amended as follows:

PART 651—NORTHEAST MULTISPECIES FISHERY

1. The authority citation for part 651 continues to read as follows:

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

§ 651.21 [Amended]

2. In § 651.21, the suspension of paragraph (a)(2) is lifted, and paragraph

(a)(5) is removed, effective June 14, 1993 through September 6, 1993.

[FR Doc. 93-14319 Filed 6-14-93; 12:42 pm]
BILLING CODE 3510-22-M

50 CFR Part 672

[Docket No. 921107-3068; I.D. 061493A]

Groundfish on the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Closure.

SUMMARY: NMFS is closing the directed fishery for pollock in Statistical Area 61 in the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the second quarterly allowance of the total allowable catch (TAC) for pollock in this area.

EFFECTIVE DATE: 12 noon, Alaska local time (A.L.T.), June 14, 1993, through 12 noon, A.L.T., July 1, 1993.

FOR FURTHER INFORMATION CONTACT: Andrew N. Smoker, Resource Management Specialist, Fisheries Management Division, NMFS, (907) 586-7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the GOA exclusive economic zone is managed by the Secretary of Commerce according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at 50 CFR parts 620 and 672.

The second quarterly allowance of pollock TAC in Statistical Area 61 is 6,239 metric tons (mt), determined in accordance with § 672.20(a)(2)(iv).

The Director of the Alaska Region, NMFS (Regional Director), has determined, in accordance with § 672.20(c)(2)(ii), that the 1993 second quarterly allowance of pollock TAC in Statistical Area 61 soon will be reached. The Regional Director established a directed fishing allowance of 5,615 mt, and has set aside the remaining 624 mt as bycatch to support other anticipated groundfish fisheries. The Regional Director has determined that the directed fishing allowance has been reached. Consequently, directed fishing for pollock in Statistical Area 61 is prohibited, effective from 12 noon A.L.T., June 14, 1993, through 12 noon, A.L.T., July 1, 1993.

Directed fishing standards for applicable gear types may be found in the regulations at § 672.20(g).

Classification

This action is taken under 50 CFR 672.20, and is in compliance with E.O. 12291.

List of Subjects in 50 CFR Part 672

Fisheries, Reporting and recordkeeping requirements.

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

Dated: June 14, 1993.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93-14311 Filed 6-14-93; 12:13 pm]

BILLING CODE 3510-22-M

Proposed Rules

Federal Register

Vol. 58, No. 115

Thursday, June 17, 1993

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 1001, 1002, 1004, 1005, 1007, 1011, 1030, 1033, 1036, 1040, 1044, 1046, 1049, 1065, 1068, 1079, 1093, 1094, 1096, 1097, 1098, 1099, 1106, 1108, 1124, 1126, 1131, 1135, and 1138

[Docket No. AO-14-A65-R02, etc.; DA-91-013]

Milk in the New England and Certain Other Marketing Areas; Extension of Time for Filing Exceptions on Proposed Amendments to Tentative Marketing Agreements and to Orders

AGENCY: Agricultural Marketing Services, USDA.

ACTION: Extension of time for filing exceptions to proposed rules.

7 CFR part	Marketing area	AO Nos.
1001 ...	New England	AO-14-A65-R02
1002 ...	New York-New Jersey	AO-71-A80-R02
1004 ...	Middle Atlantic	AO-160-A68-R02
1005 ...	Carolina	AO-388-A5-R02
1007 ...	Georgia	AO-366-A34-R02
1011 ...	Tennessee Valley	AO-251-A36-R02
1030 ...	Chicago Regional	AO-361-A29-R02
1033 ...	Ohio Valley	AO-166-A62-R02
1036 ...	Eastern Ohio-Western Pennsylvania	AO-179-A57-R02
1040 ...	Southern Michigan	AO-225-A43-R02
1044 ...	Michigan Upper Peninsula	AO-299-A27-R02
1046 ...	Louisville-Lexington-Evansville	AO-123-A63-R02
1049 ...	Indiana	AO-319-A40-R02
1065 ...	Nebraska-Western Iowa	AO-86-A48-R02
1068 ...	Upper Midwest	AO-178-A46-R02

7 CFR part	Marketing area	AO Nos.
1079 ...	Iowa	AO-295-A42-R02
1093 ...	Alabama-West Florida	AO-386-A12-R02
1094 ...	New Orleans-Mississippi	AO-103-A54-R02
1096 ...	Greater Louisiana	AO-257-A41-R02
1097 ...	Memphis-Tennessee	AO-219-A47-R02
1098 ...	Nashville, Tennessee	AO-184-A56-R02
1099 ...	Paducah, Kentucky	AO-183-A46-R02
1106 ...	Southwest Plains	AO-210-A53-R02
1108 ...	Central Arkansas	AO-243-A44-R02
1124 ...	Pacific Northwest	AO-368-A20-R02
1126 ...	Texas	AO-231-A61-R02
1131 ...	Central Arizona	AO-271-A30-R02
1135 ...	Southwestern Idaho-Eastern Oregon	AO-380-A10-R02
1138 ...	New Mexico-West Texas	AO-335-A37-R02

SUMMARY: This notice extends the time for filing exceptions to the May 11, 1993, recommended decision on Class III-A pricing for 29 Federal orders. The new deadline of June 18 is consistent with the date announced in the Department's May 21 press release.

DATES: Exceptions now are due on or before June 18, 1993.

ADDRESSES: Exceptions (six copies) should be filed with the Hearing Clerk, room 1083, South Building, United States Department of Agriculture, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Clayton H. Plumb, Chief, Order Formulation Branch, USDA/AMS/Dairy Division, room 2968, South Building, P.O. Box 96456, Washington, DC 20090-6456, (202) 720-6274.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding:

Notice of Hearing: Issued July 16, 1991; published July 22, 1991 (56 FR 33395).

Tentative Decision: Issued December 10, 1991; published December 19, 1991 (56 FR 65801) and corrected December 23, 1991 (56 FR 66482).

Revised Tentative Decision: Issued December 24, 1991; published January 2, 1992 (57 FR 15).

Interim Amendment of Orders: Issued December 27, 1991; published January 3, 1992 (57 FR 173).

Notice of Reopened Hearing: Issued August 11, 1992; published August 14, 1992 (57 FR 36609).

Notice of Reopened Hearing: Issued September 22, 1992; published September 25, 1992 (57 FR 44344).

Revised Tentative Decision: Issued October 20, 1992; published October 27, 1992 (57 FR 48575).

Interim Amendment of Orders: Issued October 29, 1992; published November 3, 1992 (57 FR 49633).

Recommended Decision: Issued May 11, 1993; published May 19, 1993 (58 FR 29133).

Preliminary Statement

Notice is hereby given that the time for filing exceptions to the May 11, 1993, recommended decision with respect to proposed amendments to the tentative marketing agreements and the orders regulating the handling of milk in the New England and 28 other marketing areas is hereby extended from June 8 to June 18, 1993.

This notice is issued 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 governing the formulation of marketing agreements and marketing orders (7 CFR part 900).

Dated: June 11, 1993.

L.P. Massaro,
Acting Administrator.

[FR Doc. 93-14331 Filed 6-15-93; 10:30 am]

BILLING CODE 3410-02-P

7 CFR Parts 1033, 1036 and 1049

[Docket Nos. AO-166-A51; AO-179-A56; and AO-319-A39; DA 90-015]

Milk in the Ohio Valley, Eastern Ohio-Western Pennsylvania, and Indiana Marketing Areas; Decision on Proposed Amendments to Marketing Agreements and to Orders

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This decision adopts changes in the Ohio Valley, Eastern Ohio-

Western Pennsylvania, and Indiana Federal milk orders based on industry proposals considered at a public hearing held August 14-17, 1990, in Columbus, Ohio, and August 28-29, 1990, in Indianapolis, Indiana. For all three orders, the decision adopts a plan for pricing milk on the basis of its protein, as well as butterfat, components. For the first time in the Federal milk order system, the proposed pricing plan includes adjustments to the protein price based on the somatic cell count of producer milk.

The decision also adopts pooling standards for producer milk and pool distributing and supply plants that will be more uniform between the three markets. Amendments to the Ohio Valley and Indiana orders will price some diverted milk at the location of the plant from which it is diverted. The decision reduces the level of the Indiana Class I price differential and amends the location adjustment provisions of the Indiana order.

Other changes to the orders include increases in the rate of maximum allowable marketing service assessments for all three orders, and an increase in the maximum allowable administrative assessment under the Eastern Ohio-Western Pennsylvania order to the level allowable under the other two orders.

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) 720-7311.

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 12291.

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 action 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 action is not intended to have retroactive effect. If adopted, this proposed action will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608(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 his 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 date of the entry of the ruling.

Prior documents in this proceeding:
Notice of Hearing: Issued July 25, 1990; published July 31, 1990 (55 FR 31056).

Notice of Reconvened Hearing: Issued August 21, 1990; published August 23, 1990 (55 FR 34569).

Recommended Decision: Issued July 30, 1992; published August 13, 1992 (57 FR 36536).

Extension of Time for Filing Exceptions: Issued September 14, 1992; published September 17, 1992 (57 FR 42899).

Preliminary Statement

A public hearing was held upon proposed amendments to the marketing agreements and the orders regulating the handling of milk in the Ohio Valley, Eastern Ohio-Western Pennsylvania, and Indiana 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 Columbus, Ohio, on August 14-17, 1990; and at Indianapolis, Indiana, on August 28-29, 1990. Notice of such hearing was issued on July 25, 1990, and published July 31, 1990 (55 FR 31056).

Upon the basis of the evidence introduced at the hearing and the record thereof, the Administrator, Agricultural Marketing Service, on July 30, 1992, filed with the Hearing Clerk, United States Department of Agriculture, his 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 material issue "1(c). Pool distributing plant definition (Orders 33 and 49).", a sentence is added at the beginning of paragraph 12, two new paragraphs are added after the second sentence of paragraph 14, the last part of paragraph 14 becomes a new paragraph with a new sentence added as the second sentence, paragraphs 15 and 33 are revised slightly, 5 paragraphs are added after paragraph 34, paragraph 35 is revised by adding a phrase in the last sentence and by adding another sentence, and a new paragraph is added at the end of 1(c).

2. Under material issue "1(d). Pool supply plant (all three orders).", two paragraphs are added after paragraph 7, and 12 paragraphs are added after paragraph 29.

3. Under material issue "1(e). Co-op pool plant (Order 33).", two paragraphs are added after paragraph 4.

4. Under material issue "1(g)(i). Diversion limits (all three orders).", 4 paragraphs are added after paragraph 13.

5. Under material issue "1(g)(ii). Pricing diverted milk (Orders 33 and 49).", five paragraphs are added after paragraph 10 and six paragraphs are added after paragraph 19.

6. Under material issue "4(a). Protein pricing.", two paragraphs are added after paragraph 29, eight paragraphs are added after paragraph 32, and three paragraphs are added after paragraph 33.

7. Under material issue "4(b). Somatic cell adjustment.", the first paragraph is revised, thirteen paragraphs are added after paragraph 15, paragraph 16 is revised, a new paragraph is added after paragraph 16, paragraphs 17 and 19 and the table following paragraph 19 are revised, paragraphs 20 and 21 are removed, and paragraph 27 is revised.

8. Under material issue "4. Multiple component pricing.", a new heading "c. Other changes.", has been added after paragraph 27 of issue 4(b), paragraphs 28 through 36 of issue 4(b) have become paragraphs 1 through 9 of issue 4(c), the first, second, and fifth through eighth paragraphs after the new heading are revised, and the ninth paragraph is deleted.

9. Under material issue "5. Class prices and location adjustments (Order 49).", eleven paragraphs are added after paragraph 11.

10. Under material issue "8. Administrative assessment (Order 36).", two paragraphs are added after paragraph 12.

11. Under material issue "10. Conforming changes.", the last paragraph is revised.

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

1. Definitions.
 - a. Route Disposition (Order 49).
 - b. Supply plant (Order 49).
 - c. Pool distributing plant (Orders 33 and 49).
 - d. Pool supply plant (all three orders).
 - e. Co-op pool plant (Orders 33 and 49).
 - f. Pool plant disaster clause (Order 49).
 - g. Producer milk.
 - i. Diversion limits (all three orders).
 - ii. Pricing diverted milk (Orders 33 and 49).
2. Reporting (Order 49).
3. Classification (Order 49).
4. Multiple component pricing (all three orders).
 - a. Protein pricing.
 - b. Somatic cell adjustment.
 - c. Other changes.
5. Class prices and location adjustments (Order 49).
6. Accountability for 9(c) milk (Order 49).
7. Payments to producers.
 - a. Due dates and late-payment charges (Order 49).
 - b. Seasonal incentive payment plan (all three orders).
8. Administrative assessment (Order 36).
9. Marketing service assessments (all three orders).
10. 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. Definitions

A number of proposals were made by several parties to amend some of the definitions under the three orders. The definitions proposed to be amended range from what were described as clarifying amendments to the route disposition and supply plant definitions under the Indiana order through the pool plant and producer milk definitions of all three orders. Most of the proposals dealing with pool plant and producer milk definitions address the issue of which plants and producers will be eligible to participate in the marketwide pools and, consequently, generated extensive testimony.

The clarifying amendments proposed by the Hoosier Milk Marketing Agency to the "Route disposition" and "Supply plant" definitions of the Indiana order should be adopted. Neither amendment

is expected to change the pool status of any entity, but will assure that the order's provisions will be more easily understood and administered.

In general, the pooling provisions of the three orders should be made more uniform. Merger of the three orders was not an issue considered at the hearing and cannot be adopted on the basis of the record of this proceeding. However, the record does show that many of the marketing conditions that normally are considered as reasons for merging Federal order marketing areas are present in these three regulated markets.

Testimony and exhibits in the record show clearly that there is a great deal of overlapping of milksheds between the Indiana and Ohio Valley markets, and between the Ohio Valley and Eastern Ohio-Western Pennsylvania markets. In addition, the record demonstrates that handlers regulated under the three orders have substantial volumes of overlapping sales, and that the order under which some handlers are regulated changes with the proportion of sales the handlers have in each order. The existence of a number of plants that operate as common reserve supplies or common surplus outlets for more than one of the markets also contributes to a picture of three very interrelated markets. In such a situation, differing levels of performance standards for pool plants and producers clearly can create inequities between handlers and producers who are competing within the same areas. Therefore, it is important that the pool plant and producer milk provisions of the orders be similar enough to assure that order provisions do not constitute artificial barriers to the participation of handlers and producers in any of the three marketwide pools.

The two major cooperative associations operating in the three marketing areas proposed amendments to the pool plant definitions that primarily would have the effect of reducing handler access to the three marketwide pools. One of the dominant cooperative associations is Milk Marketing, Inc. (MMI), which markets approximately two-thirds of the milk pooled under the Ohio Valley order (Order 33) and about two-fifths of the milk pooled under the Eastern Ohio-Western Pennsylvania order (Order 36). The other principal cooperative association is Associated Milk Producers, Inc., which pools milk through the Hoosier Milk Marketing Agency (Hoosier) in concert with MMI. Hoosier markets approximately two-thirds of the milk pooled under the Indiana order (Order 49).

Most of the amendments proposed by the two cooperatives would make participation in the three marketwide pools more difficult for handlers and producers who are not assured of a stable and significant share of the markets' fluid use. National Farmers Organization (NFO) proposed amendments to all three orders that generally would allow slightly greater participation by producers in the three pools, on a more uniform basis than currently exists. Proprietary cheese plant operators and fluid milk handlers proposed amendments to Order 36 that would have opposing effects on the ability of pool supply plants to maintain their pool status.

For Order 49, in addition to the Hoosier proposals to tighten pooling provisions, NFO, the Milk Foundation of Indiana (MFI), an organization of milk plant operators, and New Paris Creamery, a proprietary handler, made and supported proposals that primarily would allow handlers and producers to participate in the marketwide pool more easily.

A set of proposals made by Hoosier (Nos. 20, 22 and 24), to exclude from the marketwide pool producers who are paid under the "Louisville" plan of another order during that order's "payback" months, was abandoned by proponent at the hearing, and not supported by any of the hearing participants. Since the record contains no support for these proposals, they are not considered in this decision.

a. Route Disposition (Order 49)

A witness for Hoosier testified that the organization had proposed two changes to the route disposition definition. The first proposed change is to include other distributing plants, as well as other persons, in the description of milk movements that comprise "route dispositions." The witness stated that Hoosier's intention is that fluid milk products packaged for another distributing plant be included as part of the packaging plant's route sales and thus part of the computation of the packaging plant's qualification for pooling. The second proposed change would describe Class I fluid milk moved to any milk or filled milk processing plant in other than bulk form as "packaged." The Hoosier witness explained that at the present time bulk milk transferred from one distributing plant to another is not included in the route disposition calculation. He went on to say that at one time omission of bulk fluid sales from pooling qualification was justified by the pattern of milk movement in Order 49, but that such sales are used now only to

manipulate the route disposition computation for determining qualification. There was no testimony opposing the proposal, and NFO's brief supported its adoption.

Although neither change to the current order language can be considered substantive, the proposed amendments do contribute some clarification to the route disposition definition. Therefore, the proposed changes should be adopted.

b. Supply Plant (Order 49)

An amendment to the Order 49 supply plant definition proposed by Hoosier that can be considered a clarification of current order language should be adopted. The witness for Hoosier stated that the addition of the words "and is physically unloaded and received into a distributing plant" to the supply plant definition would clarify what constitutes a delivery by a supply plant to a distributing plant. The present definition of a delivery may be considered open to interpretation by those unfamiliar with the order although, in fact, a court has ruled that the present language results in the same meaning that proponents wish to spell out. For purposes of clarity, the proposed language should be adopted, but its adoption in no way implies that the meaning which is to be spelled out more fully is deficient in conveying the requirement that milk that is "shipped to" must also be "physically unloaded and received into".

c. Pool Distributing Plant

Order 33. Two changes to the pool distributing plant definition of the Ohio Valley order proposed by MMI should be denied. MMI proposed that the pool distributing plant in-area sales requirement for Order 33 be reduced from 15 percent to 10 percent of a handler's route disposition. In addition, MMI proposed increases in the total percentage of a distributing plant's receipts that must be disposed of on routes, from 40 percent to 50 percent for the months of September through February (except December), from 35 percent to 40 percent for the months of March through July, and from 35 percent to 50 percent for the month of August.

Proponent's witness stated that a decrease in the in-area sales requirement, which would increase the likelihood of a partially regulated plant becoming fully regulated, is necessary to eliminate a partially regulated handler's competitive advantage over pooled handlers on raw milk costs. The witness stated that this competitive advantage is due to partially regulated handlers

paying the equivalent of the Federal order blend price for their entire milk supply while regulated handlers must pay the Federal order Class I price for their Class I milk. The witness explained that his estimate of the cost difference between partially and fully regulated plants was between 60 cents per hundredweight and \$2.19 per hundredweight, depending on which plants were compared. The proponent witness went on to explain that due to this competitive advantage in raw milk costs, partially regulated handlers are increasing sales in the Order 33 marketing area and thus taking sales from regulated handlers. The MMI witness characterized this situation as a disorderly marketing condition that would be remedied by their proposal.

Some concern was expressed by the proponent witness that because Order 36 would continue to have a 15-percent in-area sales requirement, certain plants would become regulated under Order 33 rather than under Order 36, causing proponents difficulty in economically supplying milk to these plants. In fact, the witness stated, a handler who had initially supported the proposal was now opposed to it because a proposed amendment to Order 36 was not also included in the hearing notice, as initially intended by the proponents.

In testimony and in a post-hearing brief the MMI witness explained that the second proposed change in the Order 33 pool distributing plant definition, to increase the total route disposition percentage, was needed to increase the amount of milk available to distributing plants. He said that when the requirements were lowered, in 1984, there was a surplus of milk in the marketing area. According to the witness, however, the situation has changed dramatically to the extent that substantial volumes of milk have had to be imported to satisfy the needs of the pool distributing plants in the Order 33 marketing area. The witness also explained that the increase was needed to prevent manufacturing plants from riding the pool by paying distributing plants for the opportunity to qualify for pooling.

Proponent witness explained that August should be added to the higher total route disposition standard because August has become a relatively high Class I demand month at a time when milk production is declining. The witness explained that this higher Class I demand is primarily due to the need to begin filling school inventories.

A witness for United Dairy, Inc. (United) testified in support of the MMI proposal, stating that United had lost an account because a partially regulated

Virginia dairy had been able to offer a customer a 15- to 20-cent per gallon lower price. According to the United witness, a price difference of this size can be attributed only to a substantial difference in raw milk costs.

A witness representing Sani-Dairy, a partially regulated handler under Orders 33, 36 and 2 (New York-New Jersey), opposed adoption of the MMI proposal, and stated that no disorderly marketing conditions had been demonstrated. The witness explained that Sani-Dairy relies on uniform order provisions across the area in which it markets its products. The witness testified that at past hearings considerable effort has been made to make the provisions of Orders 33 and 36 the same. He stated that reducing the percentage of in-area route sales needed to qualify as a pool distributing plant in Order 33 without a corresponding change in Order 36 would likely cause his plant to become fully regulated under Order 33 while allowing Sani-Dairy's primary competitor in Johnstown, Pennsylvania, to avoid regulation.

The Sani-Dairy witness characterized the proposed change to Order 33 as an arbitrary change that would be disruptive and impede the free flow of goods, a result which the witness characterized as defeating the stabilizing purpose of the Federal order system. The witness also stated that Sani-Dairy needs to maintain its partially regulated status under the Federal order so it can continue to pay competitive prices to its producers.

A producer representing 133 producers shipping milk to Sani-Dairy also testified in opposition to the MMI proposal. The witness testified that if Sani-Dairy's pay price was reduced by Federal order regulation below Pennsylvania State pricing levels, he and other producers would have to consider shipping to another plant. If the price difference was significant, the producer stated, they would probably switch to another plant.

In a brief filed on behalf of Hoosier it was argued that information entered into the record for Toft Dairy, a partially regulated handler under both Orders 33 and 36, should be disregarded since it was not subject to cross-examination. Hoosier argued that Toft is able to distribute up to 15 percent of its receipts in each order without being fully regulated. The Toft information indicated that Toft pays the average of Order 33 and Order 36 Class I prices for raw milk, and argued that MMI had failed to meet the evidentiary burden necessary to justify adoption of its proposed amendment.

The portion of the MMI proposal that would reduce the in-area sales percentage requirement is the only amendment proposed by either MMI or Hoosier that would have the effect of loosening pooling standards to include more handlers in any of the three marketwide pools. Speculation by proponent witness that partially regulated handlers are able to increase sales in the regulated marketing areas because of an unfair advantage based on lower prices paid for raw milk is not a sufficient basis for reducing the in-area sales percentage at which a handler becomes fully regulated. The source of proponent's estimates of the size of two partially regulated plants about which he testified, and the magnitude of their disposition in the marketing areas (that of Order 36, as well as Order 33) was unclear, and the accuracy of the estimates was questionable. At any rate, Toft Dairy apparently represents less than .6 percent of the route disposition in the Order 33 marketing area, and approximately one-half of one percent of the Class I use in the marketing areas of Orders 33 and 36 combined. Reduction of the in-area sales percentage would, if Toft reduced its sales in order to avoid full regulation, remove from the Order 33 market fluid sales representing about .2 percent of the market's total Class I use.

Comments filed by MMI stated that the record does not reveal any insight into the value paid by Richfood Dairy, especially for sales outside the state of Virginia. However, information contained in the record about Richfood Dairy in Virginia, which apparently distributes milk in both the Order 33 and Order 36 marketing areas, indicates that the value paid by Richfood for raw milk is at least as much as the dairy's obligation would be under full Federal order regulation, because it does not incur any obligation to the Federal order pool as a partially regulated distributing plant.

Given the very small share of Order 33 Class I use that the dairies in question represent, there is no basis for trying to have the small volume of sales represented by the handlers in question become part of the marketwide pool.

The second part of the MMI proposal represents an inappropriate method of attempting to assure that an adequate supply of milk is made available for fluid use. Pool distributing plant standards exist for the purpose of determining which plants are substantially involved in distributing fluid milk products in the marketing area, and therefore should be included in the marketwide pool.

MMI exceptions in regard to Federal Order 33 charged that the hearing record had been either ignored or not read at all, and asserted that corrective action must be taken when pool distributing plants are paid a "pooling fee" to allow producer milk affiliated with manufacturing plants to ride the pool with no intention of making the milk available for Class I purposes. MMI noted that, contrary to the decision, corrective action to eliminate abuse of the system is not "inappropriate" and that pool distributing plant standards must be an integral part of "restricting producer access to the pool" if such producers are not helping to supply the Class I market when milk is truly needed.

MMI comments claimed that the Department's recommendation would allow "pool riders" and irresponsible organizations to dump surplus milk on markets in the name of "greater participation" when participation is not warranted, resulting in more disarray and less commitment to the local market. MMI asserted that the Department admitted within the recommended decision that a lack of commitment causes "problems". Additionally, MMI stated that the Dairy Division is required by law to draft decisions that contribute to orderly marketing conditions, rather than making recommendations that cause marketing problems.

There is no evidence in the record of this proceeding that would support a conclusion that a plant distributing 40 percent of its total receipts on routes during the market's months of relatively high Class I utilization is not a significant enough source of fluid milk products for the marketing area to justify its pool status. In fact, failure to regulate a plant distributing such a significant percentage of its total receipts on routes certainly could be expected to create disorderly conditions. The average Class I use percentage of milk pooled under Order 33 is barely over 55 percent, and exceeds 60 percent only about one month per year. Further, Class I use percentages do not support any argument that the pooling standard for the month of August should be increased. The record contains no basis upon which it can be determined that the current total pool distributing plant standards are not high enough. Attempts to assure that milk included in the marketwide pool is adequately associated with the fluid market are more appropriately directed at supply plant provisions.

Order 49. The pool distributing plant standards of the Indiana order should be

reduced to more closely resemble those of the adjacent Ohio Valley order so that the order under which a given plant with route sales in both marketing areas is regulated is dependent upon the marketing order with which the plant has more association. The computation of the qualifying percentage should be amended to include as receipts diversions of producer milk from distributing plants, but not transferred receipts from other distributing plants or diverted receipts from other order plants. Provisions allowing continued pool status for plants which have met pooling percentages for the previous month or during summer months for plants which have qualified during the preceding September through May should be retained in modified form.

Three proposals were made to amend the pool distributing plant standards for the Indiana order. Hoosier's proposal would reduce the minimum route disposition percentage from 50 percent to 40 percent of total receipts for the months of May through July, include diversions from distributing plants as receipts in computing qualification percentages, and remove the ability of distributing plants to qualify for pooling on the basis of their previous pool status. Generally, the proposal advanced by Hoosier would make it more difficult for handlers to qualify their plants for participation in the marketwide pool.

Proposals by the National Farmers Organization (NFO), a producer cooperative association, and Milk Foundation of Indiana (MFI), a group of six handlers regulated under Order 49, would loosen Order 49 pooling qualifications for distributing plants. NFO proposed that the required route disposition percentage be reduced from 50 percent to 35 percent year-round, but modified its proposal at the hearing to conform to the percentages included in the MFI proposal, and the current route disposition standards of Order 33. NFO's proposal would exclude diverted receipts from other order plants from the receipts used to determine qualifying percentages. The MFI proposal would reduce the percentage of a handler's receipts that must be disposed of as route dispositions if the handler's plant is to qualify for pooling from 50 percent year-round to 40 percent during the months of September through February and 35 percent for the months of March through August.

According to testimony presented by a Hoosier witness at the hearing and arguments included in a brief filed on behalf of Hoosier after the hearing, the current pool distributing plant provisions of the Indiana order allow handlers to attract and maintain receipts

of milk without making them available for Class I use. The Hoosier witness stated that many distributing plant operators want a pooled milk supply for the purpose of making Class II products or diverting milk to nonpool plants for use in cheese or Class II products. Hoosier claimed that under the current provisions a distributing plant may be pooled all year on the basis of meeting the order's pooling standards in only 5 months.

The Hoosier witness stated that the Indiana market historically is deficit in milk production, and needs a supplemental supply for fluid use. He testified that during 1989 and 1990, Hoosier imported 3 to 8 million pounds of milk per month at a cost of \$2.51 per hundredweight. The witness claimed that exclusion of milk diverted by handlers to nonpool plants from the computation of pool qualification percentages leaves a loophole for handlers to attract and maintain supplies of milk that are not made available for Class I.

According to the Hoosier witness, there is no evidence that the Hoosier proposal would result in depooling any distributing plants currently meeting pooling requirements, or impair the ability of any pool plants to remain pooled. The witness stated that the order should not allow the pooling of milk used in Class II while milk must be imported for Class I use at increased costs to handlers and consumers, and added that the Indiana market has one of the highest percentages of Class II use of the 3-class markets.

A witness for NFO testified that the cooperative markets approximately 16 million pounds of milk monthly on Order 49, and opposed Hoosier's proposals to tighten the pool distributing plant qualification requirements. NFO attributed changes in regulation of Wayne Dairy from Order 49 to Order 33, and back again to Order 49, to differences in the pooling standards for distributing plants under the two orders. As a result of the differing standards, according to NFO, Wayne Dairy was pooled on Order 33 even when the majority of the handler's sales were in the Order 49 marketing area. The cooperative asserted that changes in the order under which handlers are regulated create problems for other handlers and for producers because of the instability in the handler's regulatory status.

The NFO witness attributed Hoosier's proposals to tighten pool distributing plant requirements to former Hoosier customers changing their source of milk supply to other suppliers or to nonmembers, to an increase in the

manufacture of Class II products in several of the Order 49 distributing plants, and to the competition of these distributing plants with Hoosier plants in the Class II finished product market. The NFO witness suggested that because Class II is a substantial portion of some distributing plants' product lines, the Order 49 distributing plant Class I disposition requirement should be loosened, not tightened. The NFO witness went on to say that any perceived problem generated by increased Class II use in the market was not caused by a few distributing plants, but by the increase in Class II use by nonpool plants, particularly by Hoosier members' plants.

According to NFO, the one-month lock-in provision for Order 49 distributing plants has been a stabilizing provision that has prevented pool plants from changing regulation under different orders, and should be retained. NFO criticized the Hoosier proposal as being anti-competitive, characterizing it as designed either to cause difficulty for Hoosier competitors in participating in the Indiana pool, or discourage competitors from competing with Hoosier by producing Class II products such as condensed milk. The NFO witness favored retaining the present pooling framework and changing the qualifying percentages for pool distributing plants to agree with those effective under Orders 33 and 36.

The witness for MFI stated that a number of small distributing plants increased their Class II production as a means of utilizing their surplus butterfat, and that when they were supplied by Hoosier these distributing plants helped balance the market by using seasonal and weekend surplus milk. Since they no longer receive their supply of milk from Hoosier, they must balance their own supply. The MFI witness went on to state that since Order 49 can be characterized as a two-part market, those that are Hoosier customers and those who are not, order provisions should not contribute to the restrictive practices of Hoosier. He added that the Hoosier proposals would make retention of pool status more difficult for certain distributing plants that use significant amounts of milk in Class II, which would benefit Hoosier plants and customers who compete for the same sales.

The MFI witness pointed out that when the distributing plant provisions were written, fluid cream was considered a Class I product. Since fluid cream is now a Class II product, a plant would have had to increase its Class I route sales to maintain the same percentage for qualification. He also

stated that during the last year, Class II had made a positive contribution to the producers' blend price and that Class II should not be considered a detriment to the pool.

The MFI witness argued that Class II use in pool plants had been stable over the previous 5 years, and that the increased Class II use in the market is due to milk used by nonpool plants who have received milk diverted to them by the market's cooperative associations. The witness stated that Class II use of pool milk in nonpool plants had increased by a factor of 10 during 1989.

The post-hearing brief filed on behalf of MFI stated that while there is no evidence plants have taken advantage of the one-month lock-in provision, that provision serves the purpose of assuring that a distributing plant will not lose its pool status as a result of the loss of one large customer, but will have a month to try to increase its fluid sales to the extent necessary to meet pooling qualifications. The brief argued that ice cream operations are an integral part of pool plant operations and use seasonal surpluses caused by seasonally-reduced Class I demand and increased production. According to the brief, Hoosier would not denigrate the importance of Class II use if they thought it would be lost to the market instead of gravitating to Hoosier plants.

A witness for New Paris Creamery Company, a pool distributing plant under Order 49 and member of MFI, stated that when New Paris was a full supply customer of Hoosier, Hoosier would move milk in such a way that New Paris would remain qualified under the order. Now that Hoosier is not supplying New Paris, he testified, Hoosier characterizes the same type of milk movements in which it once participated as "sham pooling transactions."

A representative of Miller Corporation, a distributing plant operator pooled under Order 49 and a member of MFI, testified in opposition to Hoosier's proposal to tighten the pool distributing plant requirements. The Miller witness stated that he had been a full supply customer of Hoosier for many years until Miller developed a sizable market for its Class II condensed milk. He testified that Hoosier expressed unhappiness with the amount of Class II use at his plant and started assessing an extra charge for Class II products moving to other orders. The witness for Miller stated that Miller changed suppliers because Hoosier had pulled a considerable amount of milk from the Miller plant and was unhappy with Miller, and another supply became available. He continued by saying that

to a small distributing plant the loss of one account could mean the difference between being a pool plant and being a partially regulated plant. The witness indicated that in Miller's case, they would probably try very hard to maintain their pool status. He also stated that in many cases Miller's condensed product is in competition with condensed skim milk marketed by MMI, a member of Hoosier.

The record contains no justification for a higher pool distributing plant qualification percentage for Order 49 than for Order 33. These two adjoining orders share much of the same milkshed, and many of the handlers regulated under either of the orders have route disposition within the other order's marketing area. Approximately 10 percent of Indiana handlers' total route sales are within the Order 33 marketing area, and amount to over 6 percent of the total sales within the Ohio Valley marketing area.

The existence of significantly higher pooling standards in the Indiana order than in Ohio Valley can serve only as an artificial barrier that may have the effect of keeping plants pooled under Order 33 when they actually have more sales in the Indiana marketing area. As in Order 33, pool distributing plant standards should not be used as a means of restricting producer access to the pool, but solely as a means of determining which plants are significantly engaged in distributing fluid milk products in the marketing area, and which distributing plants have a close enough association with the market to justify their inclusion in the marketwide pool. Therefore, the pool distributing plant standards under the Indiana order should be relaxed to the level currently effective under the neighboring Ohio Valley order.

The receipts to be considered in calculating pool plant qualification should correspond with those included in the Ohio Valley order. The receipts to be considered, therefore, are fluid milk products received at and diverted from the distributing plant, but not bulk fluid milk products received as Class II or Class III by transfer or diversion from other plants. All producer milk for which the handler is responsible to the pool should be considered as receipts of the distributing plant, along with other fluid milk receipts for which Class II or Class III classification is not requested. Such receipts represent the supply of milk available to the handler for fluid use. Receipts of milk for which Class II or Class III classification is requested by both the selling and buying handler, however, represent a supply of milk for

which fluid use has already been precluded.

The current provisions of the Indiana pool distributing plant definition that allow a plant to retain pool status for one month after meeting the pool plant percentage requirement and allow plants which have met pooling requirements for the previous months of September through May to retain pool status for the summer months of lower Class I use should remain in the order in modified form, as long as the plant meets the order's in-area route disposition requirement during the month. Plants regulated by the Indiana order clearly have greater than average proportions of their milk used in Class II. Indiana handlers apparently use milk for Class II products consumed in other marketing areas with lower percentages of Class II use.

Although Hoosier argued that Class II use does not enhance the pool, such use clearly had added significantly to the uniform price during the year preceding the hearing, and may do so again. This increased value should be recognized by accommodating the pool status of handlers using milk in cream products and soft manufactured products.

Comments objecting to the recommended decision's failure to eliminate the "lock-in" provision from Federal Order 49 were filed by Hoosier Milk Marketing Agency and Milk Marketing Inc. The exceptors stated that the recommendation continues to allow distributing plants to be pooled on a year-round basis by meeting the Order's performance standard only five months out of 12 or by less than a 25 percent route disposition on an annual basis. The comments claimed that such an unreasonable standard in Order 49, which they described as a deficit market with high Class I utilization, makes a mockery of the Federal Order system.

Hoosier proposed a modification of the recommended decision that would allow a handler with high Class II utilization to be given a choice of retaining year-round pool status either on the basis of every other month performance or by meeting the route disposition percentage requirements during each of the months of September through May. According to Hoosier, the proposed modification would address the concerns of handlers with high Class II usage while, at the same time, insuring that milk is made available to meet the demands of the fluid market during months of greatest demand for fluid products.

MMI comments noted that while the recommended decision calls for more uniformity for the purpose of relaxing pooling standards, this criterion is not

applied when proposals call for greater participation by handlers and producers. MMI stated that the evidence weighs heavily in favor of more participation by handlers and producers in serving the Class I needs of the Indiana market, not less. Hoosier claimed that the Department rejected its proposal for pool distributing plant "reform" aimed at reducing the cost of supplying milk to fluid handlers and favored a regulatory provision that can only perpetuate and burden fluid handlers with unnecessary costs.

MMI and Hoosier noted that, contrary to the findings, a continuing need for supplemental milk to supply fluid milk requirements does exist in Order 49. MMI argued that although the NFO witness testified that his organization was willing and able to supply milk, NFO has never seemed willing to make a commitment to the Hoosier Agency, nor make milk available at a reasonable price when it is needed. MMI stated that it has had more success purchasing supplemental supplies from NFO in Wisconsin than from NFO locally, and speculated that the problem of supplying milk to fluid handlers in Indiana seems to be a pricing and commitment problem rather than a pooling standards problem.

Hoosier's and MMI's comments continue to reflect a view of distributing plant pooling standards as a means of limiting producer association with the market. Order provisions that would reduce the likelihood that a distributing plant with a significant share of its business in fluid milk sales in the marketing area would be able to maintain regular pool status would surely lead to disorderly marketing conditions. Other parties involved in marketing milk in the marketing area, both producers and handlers, could easily find themselves having to deal with continually changing conditions if the pool status of a significant fluid milk distributor changes on a frequent basis.

The provision that allows a pool plant to retain its pool status for one month after meeting pool qualifications for a month is unusual, but does exist in modified form in the Ohio Valley and Middle Atlantic orders. In a marketing area such as Indiana, where handlers have a greater than normal share of Class II use, it is entirely possible that a distributing plant losing a fluid milk customer could fail to meet pooling qualifications for a month. Disorderly marketing conditions, such as producers losing their pooling base because of a sudden loss of a handler's route dispositions, are more likely to result in the absence of the provision than to be caused by the provision. However, the

current provision should be amended to require that a handler meet at least the in-area route disposition requirement and be pooled for at least the two immediately preceding months to retain pool status. These changes should assure that any distributing plant to which the provision applies will be one with a continuing and significant role in distributing fluid milk products in the marketing area.

Similarly, the "free ride" provision for summer months is not contained in most orders, but has some utility in an order regulating the handling of milk in an area such as Indiana, which produces more than its per capita share of Class II products. Class I sales generally are at their lowest level while milk production usually increases during summer months, leaving handlers to deal with more surplus milk than during the rest of the year. Summer is also a time when demand is higher for Class II products such as ice cream and cottage cheese, and production of these products is at its highest level. Handlers who have met the distributing plant qualification percentages during the months of greatest demand for fluid products should not have to be concerned about meeting those percentages when fluid demand is low.

In comments filed by MMI, the cooperative recommended that August not be considered a "free-ride" month but rather a "transition" month when shipments should be required, but not at the same level as in other months, nor be a part of the qualification period for determining pool status during the months of June and July. This suggestion corresponds to data contained in the record. The percentage of the Indiana market's production needed for Class I use was higher in August for the period 1985-89 than for any of the months of June or July during the same period. In addition, the August Class I use percentage for any year during this period was as high as, or higher than, the Class I use percentage for the month of May. As recommended by MMI, however, it would be more appropriate to treat August as a "transition" period between months of being allowed to qualify on the previous year's dispositions and having to again meet the order's performance requirements. Therefore, August should become a month in which distributing plant pool qualification is dependent upon meeting percentage distribution requirements, but at the lower level of 30 percent.

d. Pool Supply Plant

Order 33. A proposal by Milk Marketing, Inc. (MMI), to increase the

percentage of a supply plant's receipts that must be shipped to pool distributing plants from 35 percent to 50 percent if the supply plant is to meet pooling requirements should be denied, as should the portion of the proposal that would add August to the months in which shipping percentages must be met. The proposed requirement that qualifying shipments be met on a net basis should be adopted. The portion of the proposed net shipments provision that contains an allowance for transfers or diversions from distributing plants to supply plants during holidays because of reduced Class I consumption at such times should not be adopted, although the significant reduction in fluid milk consumption during the Christmas holiday season should be recognized by reducing the required shipping percentage for the month of December to 30 percent.

A witness for MMI explained that although there were no proprietary supply plants pooled under Order 33 at the time of the hearing, one was expected to qualify for pooling in the following month. The witness asserted that higher shipping standards are necessary because the market was experiencing a shortage of milk supplies at the time of the hearing. He observed that a pool supply plant should supply the fluid market and not ride the pool, reducing blend prices to producers. The MMI witness explained that as a result of increasing the percentage, only those supply plants actually supplying the market would be pooled. He stressed the need for a net shipment provision as a means of preventing a supply plant from shipping milk to a distributing plant and then having the distributing plant return milk to the supply plant, thus defeating the purpose of allowing the supply plant to participate in the pool. The witness stated that August should be added to the qualifying months to assure a supply of milk for the market when it is needed.

A representative of the Kroger Company, a handler operating a pool distributing plant under Order 33, testified in support of the proposal to increase Order 33 pool supply plant shipping percentages. The witness stated that Kroger has spent a great deal of money procuring a supply of milk for its Order 33 distributing plant, and expressed the belief that the adoption of the MMI proposal would result in more local milk being more readily available to the Class I market, reducing costs to handlers and therefore to consumers.

Briefs filed on behalf of MMI and Hoosier supported adoption of the proposal for the purpose of increasing milk supplies available to bottling

plants and reducing the need for costly importation of supplemental supplies.

Evidence in the record fails to support any need for increased pool supply plant shipping percentages for the Ohio Valley market. In addition to the absence of any recent experience of such plants under the order or, consequently, any pooling difficulties associated with the order's present shipping percentages, the Class I use percentages for prior years do not support any increase in supply plant shipping requirements.

If supply plants were to become part of the Ohio Valley market, however, they should ship the required percentages without exchanging milk shipments with distributing plants for the purpose of evading the order's pooling standards. Therefore, the proposed net shipment provision should be adopted, without, however, including the allowances for holidays. The proposed percentage allowances for shipments of milk from distributing plants back to supply plants are needlessly complicated. For the purpose of allowing for reduced fluid milk consumption during late December, however, the shipping percentage for the month of December should be reduced to 30 percent.

The record of Class I use in the market also fails to support any need to remove August from the months during which supply plant operators who have met the order's requirements for the preceding period of relatively high Class I use may be pooled without meeting the order's shipping percentages. Increased shipments of milk for fluid use may be needed at the very end of August in order to satisfy school contracts, but such needs do not constitute a basis for requiring shipments at the full fall level for the entire month of August.

Comments opposing the Department's decision to deny a proposed increase in Federal Order 33 supply plant shipping requirements were filed by The Kroger Company (Kroger). Kroger reiterated its hearing testimony that an increase in supply plant shipping requirements combined with making August an additional qualifying month would encourage milk to move to the Class I market during months of greatest demand at a reduced cost to distributing plants, benefitting consumers of fluid dairy products. Kroger indicated that the Department's decision would allow supply plants to reap the financial benefits of participation in the pool without shipping adequate supplies of milk for the fluid market, and stated that the decision violates the primary goal of the Federal milk order program of

providing an adequate supply of milk for fluid use at a reasonable cost.

At the time of the hearing, more than three-quarters of the 16 Order 33 pool distributing plants in operation had either full or partial supply contracts with cooperative associations. It is most likely that those few distributing plants lacking such supply arrangements rely heavily on supplies of milk from nonmember producers, with supplemental supplies on an irregular basis from cooperative associations and, when available, supply plants. Given the market's supply arrangements, it is unreasonable to expect that any supply plant would be able to deliver a significant enough share of its milk on a consistent basis to distributing plants to maintain pool status if delivery requirements are set at a level near the Class I use percentage for the entire market.

Order 36. Shipping requirements for Eastern Ohio-Western Pennsylvania pool supply plants should be increased from 30 to 35 percent for the months of January and February with a provision added to require net shipments for all months, but the increases proposed by MMI and United Dairy should not be adopted. An MMI proposal that supply plants be required to transfer at least one tankerload of milk (45,000 pounds) during the fall months to maintain pool status should be adopted. A proposal by Brewster Dairy, a proprietary cheese manufacturer and supply plant operator, to allow supply plants to meet some of their qualifications for pooling on the basis of shipments to nonpool distributing plants should be denied.

Proposals by MMI and United Dairy, a proprietary pool distributing plant, would increase the amount of milk required to be moved from pool supply plants to pool distributing plants from 40 percent to 50 percent for September, October, and November, and from 30 percent to 40 percent for the remaining months of the year. The proposals also included a net shipment provision to eliminate sales back to the supply plants from pool distributing plants. The MMI proposal included a requirement that supply plants must ship at least 45,000 pounds of milk to a pool distributing plant during the months of September, October and November.

The witness for MMI explained that in recent years more and more supply plants are being pooled on Order 36. The witness went on to explain that the increase in supply plants has not increased the amount of milk available to pool distributing plants because some of these supply plants have accumulated a supply of Grade A milk and then have not performed the

function of supplying the market. According to the witness, the intended function of a supply plant is to carry a reserve supply of milk for the market and provide milk for Class I use when the market needs it. The witness stated that these supply plants have not joined the market to serve the Class I needs of the market, but to help affiliated cheese plants obtain additional supplies of milk. The witness noted that for a supply plant to provide for the fluid needs of the market, it must be able to segregate, cool, store, load, and unload Grade A milk. According to the witness, the provision in the MMI proposal that would require supply plants to transfer at least one tankerload of milk during September, October, and November would demonstrate that a supply plant has the necessary facilities to supply the market.

The MMI witness continued by noting that the supply of producer milk had declined slightly over the last eight years in Order 36, while the combined Class I and Class II needs of Order 36 had increased by 17 percent during the same period. The witness went on to explain that supply plant shipping requirements had not changed during this time and that the requirements should be changed to reflect the change in the market, particularly since supply plants are joining the market to ride the pool.

A witness for United Dairy, who also represented Hillside Dairy and R. Bruce Fike Dairy, two other Order 36 pool distributing plants, testified in support of the United Dairy proposal, which he characterized as similar or identical to the MMI proposal. According to the witness, the net shipments provision is necessary to eliminate sales back to supply plants from pool distributing plants, a practice which he said does not increase the amount of milk available to the fluid market, and therefore does not benefit the market.

The United Dairy witness stated that in Order 36, supply plants do not fulfill their function as a reserve and balancing supply for the Class I market. The witness explained that the supply plants draw millions of dollars from the Order 36 pool and yet do not supply the market when the milk is needed. The witness testified that the supply plants use the pool money to pay their producers, which, combined with premiums derived from profitable cheese operations, allows the supply plants to outpay the distributing plants and thus attract a significant portion of a diminishing Grade A milk supply. The United Dairy witness concluded that the order must contain minimum supply plant shipping percentages that reflect

the needs of the market, not only in the quantity needed but also at the times needed.

A witness for Hillside Dairy testified in support of United's proposal. The witness stated that supply plants are not releasing sufficient supplies of milk in the fall. He explained that distributing plants cannot compete with the supply plants for a supply of milk due not only to the draw the supply plants receive from the pool to pay their producers, but also the premiums they can afford to offer. The witness indicated that the supply plants can pay premiums because they can derive additional benefits from milk that distributing plants can not derive, such as higher cheese yields from higher protein milk. The Hillside witness testified that when the shipping percentages were reduced to their present levels in 1978, milk was plentiful. Since that time, he stated, the supply situation had changed, and therefore the proposed increase in the shipping percentage would enhance the marketing conditions in Order 36.

A witness representing Brewster Dairy, a pool supply plant under Order 36, testified in opposition to the MMI and United Dairy proposals, and in support of Brewster's proposal to include shipments by Order 36 supply plants to nonpool distributing plants in determining supply plant pool qualifications. The witness explained that supply plants such as Brewster serve an important function in the market by balancing the market when the demand for Class I milk does not meet the available Grade A supply. The witness noted that the supply plants not only balance the market seasonally but also on a daily, weekly, and monthly basis. The witness indicated that United Dairy's problems in acquiring milk at certain times of the year are not due to a shortage in the market, but to United Dairy's unwillingness to pay a reasonable price for the milk. The witness characterized United Dairy's problem as one of its own making, a problem that should not be remedied by regulation but by the marketplace.

The Brewster Dairy witness claimed that increasing the supply plant shipping percentage would not increase Class I use in the market but would require one sector of the market to supply milk for fluid use, thus leaving more milk for another sector of the market to use for manufacturing. Opposition to the MMI and United Dairy proposals by the Brewster Dairy witness also concerned a perceived inequity in the difference between the proposed shipping percentages for supply plants and the shipping percentages for cooperative pool plants.

The witness pointed out that in some neighboring Federal orders the shipping percentages for proprietary supply plants are the same as for cooperative supply plants and in at least one Federal order the requirements for a cooperative plant are greater than for a proprietary plant.

The Brewster witness explained that allowing proprietary pool supply plants to ship milk to other order distributing plants for qualification in Class I would enhance the Order 36 blend price and help to achieve greater equity between the two types of supply plants (proprietary and cooperative). The Brewster witness continued by stating that proprietary pool supply plants should be allowed qualifying shipments of milk to other order distributing plants for the same reasons that such shipments are allowed for cooperative supply plants. The Brewster Dairy witness' testimony in favor of the Brewster proposal was supported by two other Order 36 proprietary pool supply plants, Hans Rothenbuhler & Sons (Rothenbuhler) and Miceli Dairy Products Company.

A brief filed on behalf of the Dairy Industry Association of Pennsylvania expressed support of the MMI and United Dairy proposals to increase supply plant shipping percentages because of the difficulty of obtaining supplies of milk for Class I and Class II use, as demonstrated by temporary revisions of the shipping percentages during fall months in two recent years. The brief argued that the increased number of supply plants on the Eastern Ohio-Western Pennsylvania market has not had the effect of serving Class I needs. The supply plants were described as riding the pool during the flush production months, drawing payments from Class I handlers to pay producers the order's blend price plus premiums that enable the supply plant operators to capture a milk supply to fill their own manufacturing needs, and shipping milk out of the market during the fall months rather than supplying Order 36 distributing plants. The Association brief stressed the need for adopting a net shipments provision to make milk available for fluid use and fulfill the intent of the supply plant provision.

A brief filed on behalf of National Farmers Organization (NFO) took no position on the appropriate levels of shipment for proprietary supply plants, but suggested that higher shipping percentages could be justified for fall months because the proprietary supply plants are not required to meet qualifying percentages year-round, as cooperative plants are required to do.

The MMI and United Dairy proposals were opposed in briefs filed by Brewster Dairy and Rothenbuhler. Both briefs stated that United Dairy doesn't plan for and negotiate supplies of milk, and is unwilling to pay the prevailing rate for milk. They argued that the proposals are based on a temporary downward trend in production which, at the time of the hearing, was in the process of reversing itself. Brewster stated that no abuses were detailed in the record that warranted adoption of a net shipping standard, and asserted that there are valid reasons for distributing plants to return shipments. The brief charged that MMI wants supply plants making Class II products to have to release their supplies of milk to competing distributing plants.

The Brewster Dairy proposal to allow shipments to nonpool distributing plants to be included in determining whether supply plants meet the order's qualifying percentages was supported in briefs filed by Brewster Dairy and Rothenbuhler. The Brewster brief stated that although Brewster sells Class I milk to nonpool plants in the south and southeastern United States, the handler has also had to depool Order 36 milk because of deliveries to Order 33 pool plants because no local customer required the supplies.

Briefs filed on behalf of the Dairy Industry Association of Western Pennsylvania, United Dairy, Fike Dairy and Hillside Dairy, and MMI opposed adoption of the Brewster proposal. According to the briefs, if the proposal were adopted a supply plant could ride the pool during the flush production months while shipping only 20 percent of its receipts to pool distributing plants during the fall. The Association brief argued that Order 36 pool distributing plants should not have to pay prices consistent with both Order 36 and other markets for seasonal and spot supplies of milk.

Although the percentage of Class I use under Order 36 is generally slightly less than the same percentage under Order 33, the percentage of a supply plant's receipts that must be shipped to pool distributing plants to qualify the supply plant for pooling is 5 percentage points higher in Order 36 than in Order 33 for the months of September through November. This seeming discrepancy is explainable by differing marketing conditions and structure in the two markets. The record of this proceeding contains testimony about fluid milk handlers' difficulties in obtaining adequate supplies of milk under Order 36, while no such problems were described in relation to Order 33. In addition, only about half of the 26

Eastern Ohio-Western Pennsylvania pool distributing plants listed at the time of the hearing were described as having contracts with MMI for all or some of their milk supply, while more than three-quarters of the 16 Ohio Valley pool distributing plants were locked into a cooperative supply of milk. Clearly, a greater need exists for reliable supplies of milk at Order 36 distributing plants than for Order 33 plants, both in the proportion and number of plants that need to procure milk from sources other than the principal cooperative association.

Based on the apparent need for continued supplies of milk for Order 36 distributing plants from supply plants, there appears to be no reason to reduce the current shipping percentages to the level of Order 33. At the same time, the need to increase the shipping percentages to the levels proposed by MMI and United Dairy is not evident either. Even though the percentage of producer milk used in Class I had increased slightly in 1989 above 1987 and 1988 levels, it still represented a 10-percent decrease from the 1969-1975 period, when supply plant shipping standards were 10 percentage points higher.

It is reasonable to require that supply plants actually ship to distributing plants the percentage of their receipts specified by the order. Pooling standards that can be negated by offsetting shipments from distributing plants are meaningless. Therefore, the standards adopted should represent net shipments from supply plants to distributing plants.

The data in the record support a higher shipping standard for the months of December through February than for the "free ride" months of March through August. Class I use percentages for the market are noticeably higher during this period while schools are still in session, requiring a relatively high level of fluid milk products, and before milk production starts to increase seasonally. However, because of the customary decline in Class I use late in December, the percentage for only January and February should be increased. Therefore, the 30-percent shipping standard for all months except September through November should be increased to 35 percent for January and February and remain unchanged for the months of March through August, and December.

The MMI proposal that each supply plant be required to ship at least one tankerload of milk (at least 45,000 pounds) during the months of September, October and November to demonstrate that the plant has the

facilities to segregate, cool, store, load and unload Grade A milk is a reasonable criterion for a supply plant, and should be adopted. Proponent's testimony is unclear as to whether the intent of the proposal is to require the minimum volume of shipment in each of the three months, or in just one of the months. Establishing that a plant has the ability to handle the milk, however, should be necessary for only one of the three months, and the recommended language reflects such a requirement.

The Brewster Dairy proposal that proprietary supply plants be allowed to fulfill up to half of their required deliveries to pool distributing plants with shipments to nonpool distributing plants would not assure that Order 36 supply plants are contributing sufficiently to the supply of milk for fluid use in the Order 36 marketing area, and should be denied. Proprietary supply plants meet the order's shipping requirements for the purpose of being able to pay their producers the market's blend price, which is generated by the Class I use of pool distributing plant operators in the market under which they are pooled. It is the market's distributing plant operators who contribute the portion of the marketwide pool that exceeds the Class III price and that enables supply plant operators to pay their producers a higher price than manufacturing uses normally would generate.

Brewster Dairy apparently sells milk for fluid uses to more southerly markets during the fall months when those markets are experiencing even tighter milk supply conditions than exist in the Order 36 market. If Brewster's proposal were adopted, the handler (and other supply plant operators) would be able to use such sales as part of their qualifying shipping percentage under the Order 36 market, reap the advantages of collecting large premium payments from the southern handlers, and still maintain pool status under Order 36. Brewster would then be able to ride the Order 36 pool during the flush production months, shipping nothing to distributing plants during the months of March through August, while collecting equalization payments from the Order 36 pool to enhance its payments to its own producers.

Comments opposing an increase in supply plant shipping requirements from thirty to thirty-five percent for the months of January and February in Federal Order 36 were filed by Hans Rothenbuhler & Son (Rothenbuhler), Brewster Dairy, Miceli Dairy Products Company (Miceli), cheese manufacturing supply plant operators; and by Dairymens Oberlin Farms Dairy

(Oberlin), a distributing plant operator. The comments argued that no evidence was presented which would indicate that distributing plants experienced difficulty in obtaining Class I milk during January or February. Moreover, the comments claimed that the testimony of MMI, United, and Hillside focused on the difficulties encountered during certain fall months.

Rothenbuhler stressed that there has been no request for a temporary increase in shipping requirements during the past two years. Rothenbuhler noted that the Department recently proposed reducing shipping requirements in the Northeast-West Iowa (sic., probably Nebraska-Western Iowa), Pacific Northwest, and Great Basin orders.

Brewster Dairy claimed that there is no justification for the recommended increase in supply plant shipping requirements while at the same time the department denied Brewster's proposal to permit proprietary supply plants the same flexibility in serving Class I customers inside and outside the market as currently enjoyed by cooperatives. Brewster stated that the Department's reasoning that cooperative associations have year-round performance standards and proprietary supply plants qualify automatically from March through August is an effectively meaningless distinction because the "free ride" months are of inconsequential benefit to suppliers such as Brewster who make commitments to supply fluid customers on a year-round basis.

Comments opposing a net shipping requirement which provides that the shipments used in determining qualifying percentages shall be milk received by distributing pool plants less any transfers or diversions were filed by Miceli, Oberlin, Rothenbuhler, and Brewster. The comments claimed that supply plants serve an important balancing function by shipping to distributing plants during days of the week when demand is greatest and receiving milk from distributing plants on weekends and holidays when demand is low.

The Miceli comments stated that due to management decisions to acquire a large Italian cheese plant and producer pricing policies, the predominant cooperative operating in Federal Order 36 has encountered financial difficulties which make it difficult for the cooperative to compete for producer milk in the milkshed. Miceli and Oberlin indicated the cooperative experienced a significant drop in membership over the past two years. The exceptors claimed that passage of this amendment would reduce competition by causing the termination

of relationships between proprietary supply plants and distributing plants, forcing bottlers and cheese manufacturers to deal solely with the cooperative at much higher prices. According to exceptors, such an outcome would leave the cooperative's cheese plant as the primary outlet for fluid handlers' surplus supplies.

Miceli pointed out that although this amendment was proposed in 1990, when there was a temporary shortage of milk in Order 36, there is now an abundance of milk bordering on oversupply. Miceli stated that if the net shipping percentage amendment has to be instituted it should be done at the discretion of the local milk market administrator and not arbitrarily instituted at the behest of the only major cooperative in Order 36.

Brewster Dairy stated that if a need is demonstrated in the record for a net shipment provision the Secretary should modify the Administrator's recommendations by adopting the proposed exceptions to net shipments that are contained in the Chicago order. Brewster claimed that such modification would better encourage such services to the fluid market by operators of supply-manufacturing plants as shipments of bulk milk to the market when needed and receipts of surplus milk supplies when fluid demand is low.

Hans Rothenbuhler & Son (Rothenbuhler) complained that the proposed provision that requires supply plants in Federal Order 36 to ship at least one tankerload of milk during one of the months of September, October, or November is unnecessary. Rothenbuhler agreed that supply plants should be expected to perform the tasks of segregating, cooling, storing, loading and unloading Grade A milk. However, Rothenbuhler argued, no evidence was presented which suggests supply plants cannot currently perform these tasks. Rothenbuhler claimed that requiring milk to be actually received at a supply plant simply wastes time and resources, stating that additional transfer causes an increased risk of contamination.

Although testimony at the hearing focused on the perceived need for increasing supply plant shipping percentages for the months of September through November, the marketwide Class I use percentages for those months do not support such an increase. However, the percentages of producer milk used in Class I during the months of January and February do support an increase in the required shipping percentages for those months to a level 5 percentage points lower than the September-November level. These are months when producer deliveries

continue to be at their lowest and seasonal demand for fluid milk products remains strong. Therefore, it is appropriate to have higher shipping standards for this period, which is included in the months during which the "free ride" status is earned for later months, than for the "free ride" period. In any case, the order still contains a provision allowing the shipping percentage to be increased or decreased by up to 10 percentage points, as necessary.

The proposal of reduced shipping standards for other orders are irrelevant in determining the appropriate level of shipments for the market in question. In addition, the fact that some supply plants may have year-round commitments to supply their distributing plant customers does not assure that milk will be made available to the fluid market, in the amounts needed, during the market's months of highest Class I use.

The requirement that supply plant shipments to distributing plants be computed on a net basis does not preclude supply plants from serving a balancing function, and should not require an end to cooperative relationships between supply and distributing plant operators. The provision contained in the Chicago order that provides an allowance for milk movements between the two types of plants should be unnecessary because of the reduced level of required shipments during December and other months affected by holidays. (And, of course, all months contain Saturdays). In addition, such a provision seems unduly complicated for the needs of this market.

It is difficult to see how the market can be assured that supply plants pooled under the order are able to perform the tasks of segregating, cooling, storing, loading and unloading Grade A milk unless they are required to demonstrate their ability at some point during the year. The necessity of receiving and reloading one tankerload of milk during the months in which the market has the greatest need for a reliable supply of milk for fluid use is not onerous. The value of the time and resources expended in such an effort is exceedingly small in comparison with the benefit gained by a cheese plant operator in being able to pay its producers the blend price. Further, in a plant that is fully capable of performing the necessary operations connected with supplying milk to the fluid market, surely the risk of contamination in receiving one load of milk is not excessive.

Order 49. The portion of a Hoosier proposal to amend the Indiana order pool supply plant provision that would reduce the shipping percentage for the "free ride" period from 50 percent to 35 percent should be adopted. The percentage of milk that must be moved by supply plants to distributing plants during the months of September through February should be reduced from 50 percent to 40 percent, to bring the order more closely into agreement with the other orders involved in this proceeding. Also, pooling qualification percentages should be subject to temporary adjustment by the market administrator when marketing conditions warrant.

Proposals by New Paris Creamery and the Milk Foundation of Indiana to allow diversions of milk, as well as transfers, from supply plants to distributing plants as qualifying shipments should be adopted, up to the limit of the volume of milk transferred. An aspect of the Hoosier proposal that would shorten the "free ride" period to May through July instead of April through August should be denied. The Hoosier proposal that shipments of condensed milk re-used in fluid milk products be included in supply plant qualifying shipments has been rendered moot in light of the recommended decision [issued November 6, 1991; published November 22, 1991 (56 FR 58972)] on the record of the national hearing held in the Fall of 1990. [Docket No. AO-14-A64, etc. DA-90-017; RIN 0581-AA37].

The Hoosier witness characterized the Indiana market as a deficit market in which outside sources of milk have been needed for many years. He explained that since Hoosier supplies the majority of the supplemental milk for the market at a cost substantially above order prices, Hoosier's producers bear the brunt of the cost while other producers on the market share in the blend price, but not in the cost of supplying the market's Class I needs. The witness stated that present order provisions contribute to the problem by allowing supply plants to ride the pool.

The Hoosier representative testified that pool supply plant qualifying percentages should be computed on the basis of all producer receipts at the supply plant, including milk diverted to other plants and commercial food establishments. Other changes to the pool supply plant definition proposed by Hoosier included shortening the "free ride" period to May through July instead of April through August, allowing condensed skim milk to be used for qualification, and providing for the shipping percentages to be changed

at the discretion of the market administrator.

The witness for Hoosier explained that the shipment of milk by supply plants to pool distributing plants should be on a net basis. He stated that adoption of a net shipment provision would prevent supply plants from establishing schemes to ship fluid milk to pool distributing plants for qualification and then have the distributing plants ship the fluid milk back to the supply plant or to a nonpool plant. The witness went on to say that the Hoosier proposal would allow condensed skim milk to be used by the supply plant as part of its qualification shipments. He stated that even though this type of movement does not occur presently under the order, the use of condensed skim milk or specialty condensed mixes for fortification is a coming trend, and provision should be made for this type of movement. The witness testified that Hoosier did not intend that condensed skim milk be considered a fluid milk product.

NFO opposition to Hoosier's proposal centered around the proposed reduction in the "free-ride" period. The NFO witness stated that tightening the shipping requirements by reducing the "free-ride" period has no sound basis, and would place Order 49 supply plants at a competitive disadvantage to supply plants regulated under Order 33. The NFO witness spoke in favor of the proposed net shipments provision provided that reasonable shipping requirements are used (presumably 35 percent in March through July and December, with no change for other months). The NFO witness also supported the portion of the Hoosier proposal that would give the Market Administrator authority to adjust shipping percentages as needed.

MFI presented testimony opposing the proposal to tighten the supply plant shipping requirements. The MFI witness stated that the only change in marketing conditions in the Indiana market had been that neither of the two supply plants operating under the order at the time of the hearing marketed their milk through Hoosier, and therefore at least one of them had had to make uneconomic movements of milk to remain a supply plant under Order 49. The witness explained that even though milk is moved to qualify a plant, the movement does not result in any more milk being available for the distributing plants, and in fact some milk moves when the distributing plants do not need it. The MFI witness stated that in view of Indiana market conditions, loosening the supply plant standards would be more appropriate than

tightening the standards as proposed by Hoosier.

The MFI witness explained that the MFI proposal to amend the supply plant qualification provisions, in contrast to Hoosier's proposal, would improve the efficiency of the market by allowing supply plants to divert milk to distributing plants to meet the supply plant qualification percentage. The witness testified that many other orders allow supply plants to qualify on the basis of milk movements to distributing plants direct from farms, and that such movements are recognized as the most efficient and least cost method of supplying milk to distributing plants.

In the 20 years between the merger of the Indianapolis, Fort Wayne and Northwestern Indiana orders to form the present Indiana marketing area and the hearing in this proceeding, the percentage of Indiana producer milk used in Class I declined approximately 10 percentage points. Over the same time period, the percentages of producer milk used in Class I in the Ohio Valley and Eastern Ohio-Western Pennsylvania marketing areas declined about 15 percentage points and 10 percentage points, respectively. (Official Notice has been taken of the Annual Federal Milk Order Market Statistics for the years 1969-1990). Over the same twenty-year time period, Order 33 supply plant pooling requirements have been reduced by 15 percentage points, while the same requirements for Order 36 pool supply plants have been reduced by 10 percentage points.

It is apparent from these trends that a failure to loosen pooling provisions does not cause Class I use percentages to remain at a higher level. Also, with Class I utilization of about 60 percent annually, the Indiana market is clearly not seriously deficit in terms of milk supply for fluid uses. Although Hoosier obviously has imported large quantities of milk, sometimes at substantial cost, the market's need for such imported milk for fluid use is not clearly shown. The record indicates that some handlers have found it difficult to find fluid outlets for supplies of milk they wish to pool. Testimony by an NFO witness indicates that NFO would have been willing and able to supply some or all of the milk required by Hoosier to fulfill its supply contracts, in order to meet qualification requirements for its own milk supply. According to Hoosier testimony, 9 of the 10 fluid milk plants on the Indiana market at the time of the hearing were full or partial supply customers of Hoosier's, leaving 1 customer to be supplied by other sources.

In keeping with amendments to pool qualification provisions in Order 33 and Order 36, the Indiana pool supply plant shipping percentages should be reduced to 40 percent for the months of September through February, and to 35 percent for the months of March through August. The record provides no basis for changing the order's current "free ride" period, during which supply plants meeting the order's pooling requirements during the months of September through February retain their pool status for the following months of April through August, to May through July as proposed by Hoosier. The Class I use statistics for the previous 5 years show that the percentage of milk needed for fluid use drops sharply between the months of March and April in the Indiana market and rises most markedly between the months of August and September. In this respect the Indiana market differs slightly from the 2 Ohio markets, where the seasonal drop in Class I use is more marked between the months of February and March.

The percentage of a pool supply plant's milk supply that must be delivered to pool distributing plants should be a net requirement. As in the 2 Ohio markets, failure to adopt a net shipment requirement would result in meaningless shipping standards, and would not help to assure an adequate supply of milk for fluid use.

For the purpose of facilitating efficiencies in milk marketing, diversions of producer milk should be considered in determining supply plant qualifications, up to the amount of milk moved by transfer to distributing plants. Moving milk directly from farms to distributing plants is a more efficient way of getting milk to where it is needed than having to unload and reload the milk at supply plants. In addition, extra unloading and reloading increases the cost to handlers of handling milk and causes the milk to deteriorate in quality. Direct delivery by supply plants from producers' farms to distributing plants supplies the market just as transfers do, but at a lower cost.

Milk diverted by a supply plant operator should be considered a receipt at the plant for the purpose of determining pool qualification, as should .9(c) milk received from a cooperative association. Such milk constitutes the supply of producer milk available to the handler for shipment to distributing plants. In addition, allowing diversions of producer milk to be included as qualifying shipments necessitates that such movements be considered as receipts. Receipts of other source milk or transfers and diversions for which Class II or III classification is

requested by both the shipping handler and receiving supply plant handler do not need to be considered as receipts for qualification purposes.

Provision should be made in the pool plant definition for the market administrator to temporarily adjust the percentage shipping requirement by up to 10 percentage points if such action is needed to assure an adequate supply of milk for fluid use, or to prevent uneconomic shipments of milk. Such a provision will allow more efficiency in adjusting regulations to marketing conditions.

e. Co-op Pool Plant

Order 33. A proposal by National Farmers Organization (NFO) to reduce the shipping percentages required of a cooperative association plant from 50 to 35 percent should be adopted. The modification to the proposal made by proponent at the hearing, to eliminate the requirement that qualifying shipments be to pool plants instead of to pool distributing plants, should not be adopted. The NFO witness testified that NFO's proposal to change the cooperative pool plant shipping percentage in Order 33 to equal the Order 36 cooperative pool plant shipping percentage would further NFO's goal of making the provisions of the 2 Ohio orders more uniform. The witness explained that the Class I utilization of the two orders was almost equal in 1989, and that no other parties at the hearing had proposed increasing the cooperative pool plant shipping percentages effective under Order 36. The NFO witness further stated that a long-time fluid milk customer had ceased bottling activity, causing NFO difficulty in meeting the order's pooling requirements.

The proposal was opposed by MMI and Hoosier on the basis that shipping requirements under Order 33 should be tightened, not loosened. The MMI brief argued that there is no reason to reduce shipping requirements in a market with 80 percent Class I and Class II use. The brief filed on behalf of Hoosier stated that the NFO plant at McCartyville is only 15 miles from the MMI New Bremen plant to which some of the NFO milk is delivered. The Hoosier brief stated that the NFO facility is a reload point, not an actual plant with the ability to cool or hold milk, and that its operation makes no economic sense and serves no balancing function for the market. The Hoosier brief also argued that NFO moves milk to its own plant first to multiply the pounds of milk it can qualify for pooling on the basis of sales to New Bremen and other handlers.

The current language of the order makes very clear that a cooperative pool plant can qualify for pooling only if 50 percent of the association's member producer milk is actually delivered to pool distributing plants, and leaves no room at all for pyramiding additional volumes of pooled milk on top of the milk which is qualified at the cooperative pool plant. In view of the Class I use percentage of the Ohio Valley market and the portion of the market dominated by MMI, it is unreasonable to require a cooperative association to deliver 50 percent of its milk supply to pool distributing plants on a year-round basis. Reduction of the required percentage to 35 percent will still require that cooperatives operating cooperative pool plants demonstrate a higher level of commitment to supplying the fluid market than regular supply plants must meet because supply plants that meet the 35-percent shipping percentage requirement for the months of September through February do not have to do so during the months of March through August. There is no reason to require cooperative pool plants to meet a significantly higher shipping percentage than regular supply plants, as well as meeting such a percentage on an average annual basis.

The proposal to allow any shipments to pool plants as qualifying, however, or to include shipments to nonpool distributing plants in cooperative pool plant qualification, would have the effect of ignoring the responsibility of such plants to supply the market for fluid use within the Ohio Valley Federal milk order marketing area. Therefore, these modifications to the proposal should not be adopted.

MMI filed exceptions to the recommended reduction in Order 33 cooperative pool plant shipping standards on the basis that the cooperative finds no justification for lowering standards in the Ohio Valley market. The cooperative observed that the market performed more smoothly when milk supplies declined, and stated that cooperative associations that have made a commitment to the fluid market, made an effort to deliver high-quality milk and not made unrealistic statements to their members have not had any difficulty in meeting pooling standards.

The justification for lowering the shipping requirements in question is set forth above. Further, the comment that the market performed more smoothly when milk production declined is no doubt true because in that situation the current performance standards were not unrealistically high. As milk production has increased, reductions in shipping

standards have become necessary in order to prevent inefficient and uneconomic shipments of milk from occurring solely for the purpose of meeting the order's pooling requirements.

Order 49. A proposal by NFO that a cooperative pool plant provision be added to the Indiana order should not be adopted. The NFO witness stated that NFO's proposal was patterned after similar provisions in Order 33 and Order 36 where, he said, the cooperative supply plant provision has been a positive method of efficiently pooling the milk of cooperative members. The witness explained that this provision would allow the most efficient pooling of NFO's supply plant and the cooperative's total milk supply. The provision would allow a cooperative to qualify a cooperative supply plant if the cooperative shipped 35 percent of its total producer milk on the market year-round to pool distributing plants.

The proposal was opposed in a brief filed on behalf of Hoosier on the basis that the Indiana marketing area does not need supply plants, and has never needed a balancing plant. According to Hoosier, the NFO Madison plant doesn't serve the purpose of a balancing plant because it provides no processing of the market's reserve supplies.

The record provides no indication that a cooperative pool plant provision is needed in the Indiana order. There was no testimony that milk must be transferred from farm pick-up routes to over-the-road tankers to assure Indiana fluid milk handlers of a milk supply. The producer milk diversion allowances, relaxed under this decision, should allow NFO to continue to qualify its member producer milk associated with the Indiana market to retain pool status without adding an unnecessary provision to the order.

f. Pool Plant Disaster Clause (Order 49)

A "disaster clause" proposed by Hoosier for inclusion in the Indiana order should be adopted. The proposal would assure continued pool status for pool distributing and pool supply plants if a plant was unable to meet the order's pooling standards because of disastrous circumstances. Proponent witness defined such disasters as unavoidable circumstances such as natural weather-related events, fires, breakdowns and work stoppages, and proposed that relief be limited to two consecutive months to prevent abuse.

No opposition to the proposal was expressed at the hearing, and the NFO brief filed on the basis of the hearing record supported the proposal as preserving orderly marketing in the

event of natural disasters or other events that could interfere with pool plant status. An order provision assuring continued pool status in the event of an unforeseen and unavoidable circumstance that is not a result of a handler's business decisions should enhance the orderly marketing of milk in the Indiana marketing area. Such provisions have worked well in other orders over a number of years. Therefore, the proposal should be adopted.

g. Producer Milk

(i) Diversion limits (all three orders).

A proposal by NFO to make the diversion limits uniform between the three orders should be adopted. The amended orders would allow 50 percent of a handler's producer milk to be diverted during the months of September through February, except for the month of December when the allowable percentage of diversions would be 60 percent. Diversions during the months of March through August would continue to be unlimited. During the months of September through November at least one day's production of each producer's milk would have to be received at a pool plant. Proposals to eliminate requirements in Orders 36 and 49 that producer milk be received at pool plants before being eligible for diversion are adopted.

The NFO witness testified that the NFO proposal to amend the producer milk definitions of the three orders to achieve a higher degree of uniformity is based on the high degree of interrelation between the three marketing areas. The witness stated that NFO's proposal would achieve uniformity by (a) requiring each producer to "touch base" at a pool plant during each month of September through November, as is currently the case under Orders 33 and 36, (b) allowing a producer's milk to be diverted to a nonpool plant prior to being received at a pool plant, and (c) establishing a uniform 50-percent diversion limit for the months of September through February, excluding December.

NFO's proposal was opposed in briefs filed on behalf of MMI and Hoosier, wherein it was argued that the proposed diversion limits would liberalize and reduce shipping standards that are needed to protect the integrity of the pools and insure an adequate supply of milk for fluid use. In addition, Hoosier's brief stated that the pooling provisions of each order are established on the basis of production and marketing data unique to each. The brief argued that if the uniformity argument is not specious, the pooling provisions of Order 49

should also conform with those of Orders 30, 40, 32, 50 and 46.

NFO's proposed amendment to Order 36 would enable producers to maintain their producer status after a break in deliveries (such as in the case of a degrade) without having to touch base at a pool plant, as long as their milk has not been pooled under another order since being pooled under Order 36. The witness explained that under the present provisions of Order 36 a producer must maintain continuous association with the market to be diverted, even during those months when there is no touch-base requirement. According to the witness, uneconomical movements of milk result when a producer temporarily loses Grade A status. In such a case, the producer's first day's production upon returning to the market must be received at a pool plant, requiring that the entire load with which the producer's milk is picked up be received at a pool plant, and resulting in uneconomical and unnecessary movements of milk. The witness explained that NFO's proposal would allow a producer's milk to be diverted before being received at a pool plant if the producer has not been associated with another Federal order during the time the milk was not pooled. No testimony or briefs were received opposing the NFO proposal to amend the Order 36 producer milk provisions.

A proposal by Milk Marketing, Inc., to amend Order 36 would limit March through August diversions of producers with less than one-third of their milk pooled during the preceding months of September through November. The MMI witness stated that producers who share in proceeds from the fluid market during the flush production months should be expected to deliver some milk to market when it is most needed for Class I. The MMI brief referred to testimony in the record that some producers ship milk south in the fall and ride the Order 36 pool in the spring. The proposal was characterized by MMI as similar to provisions in other markets.

NFO opposed adoption of the proposal on the basis that it would be difficult if not impossible to administer. The NFO brief described the MMI proposal as an attempt to penalize or restrict movement of producers off of Order 36 and back on again. According to NFO, no problem necessitating adoption of the proposal was demonstrated at the hearing. The Dairy Industry Association of Pennsylvania filed a brief stating that the Association had no objection to the proposal if producers' milk may be diverted

without limit in December and March through August when one-third of the producers' milk is pooled during the months of September through November.

The MMI proposal should not be adopted. The amended producer milk provisions should provide sufficient assurance that producers whose milk is qualified for pooling are adequately associated with the fluid market to share in the proceeds of the marketwide pool. The record contains little or no basis to support adoption of the proposal.

A proposal by Hoosier for Order 49 would amend the producer milk definition to allow producers to "touch base" at pool plants any time during a month, allow producer milk to be diverted to commercial food processors as well as to nonpool plants, and remove April and August from the months in which unlimited diversions are allowed. A brief filed on behalf of NFO supported the portions of the proposal that would allow diversions of producer milk to commercial food processors and allow a new producer's milk to be diverted before it is received at a pool plant. NFO opposed tightening Order 49 delivery standards, arguing that if Order 49 standards are significantly higher than those under Order 33, the result will be more milk pooled under Order 33 rather than more milk available to Order 49 pool distributing plants.

As adopted herein, the Indiana producer milk definition will allow producers to "touch base" at pool plants at any time during each of the months of September through November, for the same reasons of efficient hauling and handling that such provisions were adopted for Order 36. In addition, the November 1991 decision on the 1990 national hearing adopts provisions that allow producer milk to be diverted to commercial food processing establishments. Therefore, that issue is not addressed in this decision. Finally, the record provides no basis for tightening Indiana diversion provisions.

All of the ways in which the milk marketing activities of these three markets overlap support the argument that producer milk diversion limits should be more uniform between the three orders. The milkshed of the Ohio Valley marketing area overlaps significantly with those of the Eastern Ohio-Western Pennsylvania and Indiana marketing areas, to the extent that in December 1989 nearly 80 percent of the milk pooled under Order 33 was produced in counties which also supplied milk to Orders 36 and 49. Over 60 percent of the producer milk pooled under the Ohio Valley order was

produced in the common milkshed with Order 49, while over 20 percent of the producer milk pooled under the Indiana order was produced in the common Order 33-Order 49 milkshed. Further, milk was pooled under Order 33 in 1990 from 12 counties in Indiana and Michigan that did not supply milk to Order 33 handlers in 1988 or 1989 but did supply Order 49 handlers, and from 6 Michigan, Pennsylvania and Ohio counties that did not supply milk to Order 33 handlers in 1988 or 1989 but did supply Order 36 handlers, indicating significant levels of changes in market by producers among the three markets.

The outlets for surplus milk supplies used by the three markets also demonstrate a high degree of interrelationship. During 1989 and 1990, 21 nonpool plants were listed as recipients of Class II and Class III milk from both Order 33 and Order 36, while 13 nonpool plants were listed as receiving surplus milk from handlers regulated under Orders 33 and 49. Ten nonpool plants received Class II and Class III milk from handlers regulated under Orders 36 and 49 in 1990, and 11 nonpool plants received Class II and Class III milk from handlers regulated under all three orders during the period 1985-90.

Two pool distributing plants, Smith Dairy and Wayne Dairy, shifted between orders in both 1989 and 1990; Smith Dairy becoming pooled under Order 33 instead of Order 36 during some fall months of both years, and Wayne Dairy shifting regulation from Order 49 to Order 33 during the summer of 1989 and fall of 1990. In addition, at the time of the hearing, the Shipshewanna supply plant was expected to shift regulation from Order 49 to Order 33. The effect of a shift in the order under which a plant is regulated will be disorderly for producers if they fail to meet the delivery requirements of the order under which they find their handler regulated, instead of the requirements of the order under which their handler had been regulated.

As noted earlier, the pooling provisions of the Indiana order have failed to be adjusted in accordance with marketing conditions as milk production pooled under the order has increased faster than Class I sales by regulated handlers. For this reason, and because of the need for uniformity between provisions of the three orders as outlined above, the producer shipping percentages of the three orders should be amended as proposed by NFO.

Milk Marketing, Inc., filed comments opposing the recommendation to

liberalize diversion allowances for all three orders and the denial of MMI's proposal for Order 36 to limit March through August diversions of milk from producers who had less than one-third of their milk pooled during the previous September through November period. MMI stated that evidence on the record indicates that handlers have used the three markets as "dumping grounds" after taking advantage of high premiums payments from other markets, but failed to cite such evidence. MMI claimed that although there is considerable overlap between Orders 33, 36, and 49, marketing conditions between the markets are different. MMI indicated that the Order 36 milkshed traditionally has had more than an adequate supply of producer milk to meet the Class I and Class II needs of the market without incurring significant transportation costs. In contrast, MMI claimed, a substantial amount of milk must be moved long distances in Orders 33 and 49 for delivery to processing plants.

MMI noted that provisions which allow milk not continuously affiliated with the market to ride the pool during the flush months are inequitable and will lead to more disorderly conditions. The cooperative stated that denial of its proposal is inconsistent with denial of the Brewster Dairy proposal to allow supply plants to include shipments to nonpool distributing plants in calculating supply plant pool qualifications. MMI stated that the Department apparently approves of moving milk as producer milk to other markets while not approving of plant transfers for the same purpose.

As noted by MMI in its exceptions, marketing conditions do differ somewhat between the three markets. However, the degree of overlap in production and distribution between the markets makes it necessary for the orders' diversion limits to be equitable, as described above. In fact, the differences in pooling provisions between the three orders may be as much a cause as an effect of the differing marketing conditions.

With regard to denial of the MMI proposal to preclude from unlimited diversions during the months of March through August the milk of producers who had less than one-third of their milk pooled during the preceding September through November, such a denial is not inconsistent with the denial of the Brewster Dairy proposal to consider diversions to nonpool distributing plants as part of a supply plant's qualifying shipments. Under the terms of Order 36 as adopted herein, producers participating in the pool cannot have their milk pooled under

another order during the period between its physical receipt at an Order 36 pool plant and its diversion under Order 36 to a nonpool plant. The order also provides that milk diverted to another order plant can be producer milk only if moved for Class II or III use under the other order. Therefore, this decision is consistent in disallowing milk moved to other order plants for Class I use from participating in the Order 36 pool.

ii. Pricing diverted milk (Orders 33 and 49). Order 33. A proposal by MMI to amend the Ohio Valley order to price milk diverted to plants located outside the marketing area and outside the State of Ohio from farms located inside Ohio or in five Michigan counties at the location of the plant from which diverted should be adopted, with some modification. At the time of the hearing, proponent modified the proposal to require that producers whose milk is priced at the location of the plant from which it is diverted deliver at least 66 percent, or 20 days' production, of their milk to pool plants during each of the months of September, October and November. The proposal as adopted would be further modified by limiting the location adjustment applicable to the uniform price paid to such producer to that effective at the location of the producer's farm for the months of March through August, but only when 65 percent of a producer's milk is delivered to a pool plant or plants at which an equivalent or higher price is applicable during the months of September through February.

The MMI witness stated that every fluid milk market needs facilities or access to facilities to handle reserve supplies of milk that are not needed for fluid use on weekends and holidays. He testified that the number of manufacturing plants in the Order 33 marketing area has decreased to such an extent that on many occasions milk not needed for the Class I market must be moved long distances to be processed into storable products. According to the witness, milk produced outside the marketing area near the reserve processing plants creates no difficulty, but that milk produced within the marketing area that must be transported outside the area to manufacturing plants does create financial problems.

The witness testified that producers whose milk is moved to distant plants (located at Goshen and Auburn, Indiana) expect to be subject to prices and hauling rates competitive with their neighbors whose milk goes to nearby fluid outlets. He explained that disruptive and disorderly marketing conditions would occur if individual dairy farmers began competing for the

local market and trying to avoid the cost of sending their milk to distant plants and receiving a lower blend price as well. The MMI witness argued that producers who have diverted their milk from local markets have already suffered financial loss due to increased hauling, and should not be subject to the additional loss of receiving a lower blend price as well. However, the witness also testified that producers pay a fixed rate for hauling under their contracts with haulers, regardless of the destination of their milk. Proponent cited what he described as similar provisions to those proposed for the Ohio Valley order in the current Southern Michigan order and former Lake Mead order.

It appears that adoption of the proposal may have the effect of causing milk to be moved to Goshen rather than to fluid plants in the southern part of the marketing area, where much less milk is produced and where more milk is needed for fluid use. The distance from New Bremen, Ohio, where much of the milk in question is normally received, to the surplus outlet at Goshen, Indiana, (about 120 miles) is about the same as the distance from New Bremen to Cincinnati, Ohio, in the southern part of the Ohio Valley marketing area. The ability of producers to easily receive the same price for deliveries to a surplus outlet as they would if their milk had gone to a nearby plant would remove the incentive intended by the order's location adjustment provisions to move milk to the more southerly part of the marketing area where it is needed.

Three-quarters of the distributing plants, at which milk is needed for fluid use, that are pooled under the Ohio Valley order are located south of Zone 2 and south of the area of heavy milk production in which the MMI witness indicated producers experience problems with additional negative location adjustments. In fact, in December 1989 over 50 percent of the Ohio milk pooled under Order 33 was produced in the Ohio counties of the Ohio Valley marketing area north of Zone 3, while less than 40 percent of the Ohio milk pooled under Order 33 was produced south of Zone 2. With less than 40 percent of Ohio milk available from nearby sources to supply approximately 75 percent of the Class I needs of the market, it is apparent that the need for price incentives to move milk from the heavy production area of northern Ohio to the southern Ohio area of greater Class I demand still exists in the market. Therefore, the incentives contained in the current location adjustment structure of the market

should not be curtailed as abruptly as proposed by MMI.

The provisions of the Southern Michigan order and the former Lake Mead order differ significantly from those proposed by MMI. Under the Southern Michigan order, only the milk of producers who each month deliver 65 percent of their production to plants at which the same location adjustment rate is applicable are eligible to have all of their milk deliveries subject to that same rate, rather than a lower rate for milk diverted to distant manufacturing outlets. The Lake Mead order provided that only those producers located in two counties for which the only nearby outlet was a fluid milk plant in Las Vegas, Nevada, would have their milk priced at the plant from which diverted. The location adjustment on prices paid to producers located in the vicinity of a distant manufacturing plant was capped at the rate applicable at that plant. Similar provisions for the Ohio Valley order would allow pricing at the location from which diverted only for the milk of producers located in the Cincinnati area, and require the assumption that the nearest surplus outlet is in Goshen, Indiana.

According to the record of this proceeding, there are at least six nonpool plants located in Zones 1 and 2 of the Ohio Valley marketing area and the three northwestern Ohio counties that lie between the Order 33 and Order 49 marketing areas that receive Class II and Class III milk from pool plants for use in the manufacture of ice cream, yogurt, and evaporated milk. A number of surplus outlets also exist in Zones 3 and 4 for milk usually delivered to pool plants in that area that must be diverted from fluid use at times when the fluid plants do not need it. These plants certainly represent closer surplus outlets for the milk of producers in northern Ohio and southern Michigan than the Goshen facility, as does a Kraft ice cream plant in Huntington, Indiana.

Although proponent witness referred specifically to problems encountered in the diversion of producer milk to manufacturing outlets on weekends and holidays, it is apparent from seasonal production and fluid use statistics that a greater problem exists in connection with moving surplus milk to manufacturing outlets in the spring and summer months when production increases and fluid milk needs decline.

For the period March 1987 through February 1988, which apparently was unaffected by any shift in plant regulation under Order 33, the average daily volume of producer milk used in Class III during the months of March through August exceeded the average

daily Class III use for the following September through February period by more than 130 percent, or over 1,600,000 pounds per day. In view of the availability of some nearby manufacturing plants and the wide seasonal variation in the amount of surplus milk that must be disposed of, changes in the pricing of diverted producer milk should be confined to the season in which significant volumes of surplus milk are produced. Further, those producers who benefit from the amended provision should not benefit to the extent of having milk that is diverted to a lower-priced area priced at the same rate as if it were received at a plant in a higher-priced zone. In order to avoid such a situation, the location adjustment provisions should limit the price paid for diverted milk to the price effective for the zone in which the farm is located.

The provisions adopted in this decision will assure that the order retains a price incentive to move milk from the northern area of heavy production for the Ohio Valley market to southern Ohio, where consumption is greater relative to production. Only producers whose milk is regularly received at pool plants during the months when supply plants are required to ship milk to distributing plants should be eligible to have their diverted milk priced at the plants where it is regularly received rather than at reserve processing plants. Adoption of a provision pricing most milk at the location from which it is diverted, even if applicable only to producers in a particular vicinity, would provide a disincentive to move milk from farm locations to the cities where it is needed for fluid use.

Although MMI's comments expressed pleasure at the recommended decision's acknowledgment that milk produced in excess of fluid needs must be moved away from the primary market, dissatisfaction was expressed with several aspects of the decision. The comments indicated an MMI concern that the decision has an unequal impact on the cooperative as compared with other producers and ignores the price difference between Cincinnati and New Bremen. MMI's comments argued that the decision overstated the number and location of nonpool plants in the marketing area. MMI stated that it would be more appropriate to price milk at the plant from which diverted rather than the farm location because hauling rates and prices at neighboring farms do not change just because milk is diverted away from the market. The cooperative also suggested that the month of December should be added to the

months for which location adjustments on diverted milk are altered.

The decision should not affect cooperative members and nonmembers inequitably, since the revised order language does not require a higher level of performance of cooperative members and applies to all producers. Although there is a 21-cent price difference between New Bremen and Cincinnati, such a difference amounts to only about 1.6 cents per hundredweight per 10 miles, or significantly less than the amount required to move the milk. The current location adjustment rate cannot be expected to provide enough of an incentive to cause milk to move long distances to pool plants when the milk is needed at the cooperative's manufacturing plant to maintain the desired level of operation. The number and location of nonpool plants that were cited in the recommended decision as being closer than Goshen to the Order 33 production area was derived from the only information available in the hearing record regarding such facilities.

MMI's argument that its member producers on neighboring farms should be subject to the same hauling rates and prices disregards MMI's own testimony that the co-op's members pay a fixed rate for hauling under their contracts with haulers, regardless of destination, and overlooks the rebinding privilege available to cooperative associations. That privilege allows MMI to assure that its members located on adjoining farms would receive the same price for their milk, regardless of its destination. Further, the price received at the location to which milk is customarily delivered is irrelevant to the appropriate price to be paid for diverted milk.

The amendment is adopted as a means of assuring that producers whose milk must be diverted to distant manufacturing plants are not unfairly penalized for such movements in addition to any extra hauling charges that may be incurred. It would be inequitable to assure that such diversions would result in the same return as movements of needed milk to distributing plants located in higher-priced zones.

Data in the hearing record indicate that the percentage of producer milk used in Class I in December under Order 33 is as high or higher than in the other months included in the September through February period. Therefore, it should not be necessary to include December as a month for which diverted milk is not subject to location adjustments.

Order 49. A proposal by the Milk Foundation of Indiana (MFI) to price all diverted milk at the location at which it

is received instead of the location from which it is diverted should be adopted, with modifications. MFI, a group of proprietary distributing plant operators, proposed the deletion of a provision of the Indiana order that allows milk diverted to a plant located in the marketing area, the State of Ohio, or south of the marketing area to be priced at the plant from which diverted. The witness for MFI stated that the provision allows Hoosier to take as much as \$60,000 a month out of the pool by moving milk to nonpool manufacturing plants for surplus use instead of to fluid milk plants for Class I use, as normally intended by location adjustment provisions.

A portion of Hoosier's proposal to amend the producer milk definition would have provided for diverted milk to be priced at the location of the last pool plant from which it was diverted, and, in the case of a dairy farmer who was not pooled under the order in the prior month, for such milk to be priced at the location at which it is first received.

MFI's proposal was opposed by Hoosier and Milk Marketing, Inc., on the basis that producers who normally deliver milk to a particular plant expect to receive the price paid at that location, not a lower price when their milk must be diverted to a distant plant for which they incur higher hauling costs. According to the brief filed by Hoosier, the Indiana market is unlike most Midwest areas, in that diverted milk pooled under the Indiana order primarily moves from inside the marketing area to the periphery, instead of from the periphery to the center. Further, the brief stated, Indiana differs from many Midwest areas where the milk supply is located to the north of the fluid handlers and location adjustments are needed to avoid paying "phantom freight" for diversions of milk to nearby manufacturing plants. The Hoosier brief stated that there is no "phantom freight" in Order 49, and that the present provision is justified on the same basis as the Lake Mead provision referred to in relation to the Ohio Valley location pricing proposal.

Hoosier explained that many of its producers are located near handlers to which milk is delivered when needed. When not needed by fluid handlers, the brief stated, the milk is diverted to a balancing outlet some miles distant. Hoosier argued that such producers should not be penalized by receiving lower prices for their milk that must be diverted, as well as incurring higher hauling costs.

Hoosier's argument that diverted Indiana pool milk moves from the

center of the market to the periphery, and not from a northern production area, is contradicted by record evidence. According to data in the record, milk production in the northern part of the Indiana market is much heavier in relation to fluid needs than is the case in the southern part of the market. Sixty percent of the milk produced for the Indiana market is produced in the northern part of the marketing area, where the primary surplus outlets are also located and where negative location adjustments are effective. A number of other surplus outlets are located in Illinois, where minus location adjustments apply, and in Ohio Valley zones with lower Class I differentials under Order 33 than under the Indiana base zone, but subject to no location adjustments under the Indiana order.

Only one-half to two-thirds of the volume of milk used in Class I in the Indiana zero adjustment zone is produced there. Similarly, seventy to ninety percent of the milk needed for Class I use in the minus 20-cent zone, just north of the zero zone, is produced within the minus 20-cent zone. Eighty-five to ninety percent of the Indiana Class I milk is distributed from plants located in the zero and minus 20-cent zones, but less than 40 percent of the milk in the pool is produced in the Indiana portion of the zero and minus 20-cent zones where the distributing plants are located.

The need for supplemental milk supplies in the two southern zones of the Indiana order makes it clear that the order should provide some incentive for milk to be moved from northern Indiana, Ohio and southern Michigan, where it is produced, to southern and central Indiana distributing plants. The present order provisions, allowing milk to be priced at the plant from which diverted, contain no economic incentive to move milk to where it is needed for fluid use. Provisions similar to those adopted for the Ohio Valley order, as explained above, should provide the needed economic incentive to move milk for fluid use without unduly penalizing handlers who must move milk to distant manufacturing plants when their milk supplies are not needed for fluid use.

Because of the dearth of outlets for surplus milk in the southern portion of the Indiana marketing area, the diverted milk of producers who meet the 65-percent shipping requirement to pool plants in the southern zones during any month should not be subject to any additional minus location adjustments. However, milk delivered primarily to locations in the northern part of the marketing area, in which most of the

primary surplus outlets are located, should be priced at the plant at which it is physically received. Such provisions will assure that producers whose milk is usually received in the lower-priced northern portion of the market will have a price incentive to allow their milk to be moved south, where it is more likely to be needed for fluid use. In addition, the provisions adopted in this decision will more closely resemble the Southern Michigan and Lake Mead provisions cited by Hoosier and MMI than do the current Indiana order provisions regulating the pricing of diverted milk.

For the reasons stated above, the Indiana order should require that 65 percent of a producer's milk be delivered to a pool plant or plants in the current zero and minus 20-cent pricing zones of the marketing area during any month in order to have the producer's diverted milk priced at the location from which diverted. Milk customarily delivered elsewhere should be priced at the location at which it is physically received.

Comments regarding the recommended decision for Federal Order 49 to price diverted milk at the location at which it is received instead of the location of the plant from which it is diverted, with some modifications, were submitted by Hoosier Milk Marketing Agency and Milk Foundation of Indiana.

Hoosier's comments stated that the amending language of the recommended decision failed to account or provide clearly for the manner of pricing diverted milk of producers located in the plus 10-cent, zero, and minus 10-cent, zones of the marketing area, or in the 35-cent zones when 65 percent or more of such milk is delivered to a zero or proposed minus 10-cent zone handler. Hoosier observed that the stated intention of the decision is not to allow the price for the diverted milk of a producer located in the minus 35-cent zone, who delivers to a zero zone plant 65 percent or more of the time and whose milk is diverted to a minus 20-cent zone plant, to be adjusted downward to the uniform price applicable to the (minus 35-cent) location of the producer's farm, even though the milk was received at 20-cent location plant. Hoosier argued that the diverted milk of any producer should be priced at the location of the plant from which the milk is diverted as long as 65 percent or more of the producer's milk is delivered to a zero, minus 10, or plus 10-cent plant location in any month.

Milk Foundation of Indiana comments asserted that the proposed order language does not provide for

producers in such counties as Jefferson, Washington, Scott, and others (in the plus 10-cent zone). MFI stated that a producer in those counties could not qualify under the 65 percent provision since there are no plants "at which the same or higher uniform price is applicable" to which the milk could be moved economically. MFI suggested a modification to the recommended order language that would eliminate the discrepancy.

Hoosier's concern about the minus 35-cent zone producer who delivers milk to a minus 20-cent zone plant is unfounded. The amended order language provides that the uniform price for such milk not be adjusted downward below the uniform price applicable at the location of the producer's farm. The language does not require (nor intend) that the uniform price be adjusted below the price applicable at the location to which the milk is delivered.

The MFI comments regarding producers located in the plus 10-cent zone warrant a slight modification to the recommended order amendments to specify more clearly the area in which 65 percent or more of a producer's milk must be delivered if diversions outside that area are to be priced at the location of the farm.

Hoosier's assertion that diverted milk should be priced at the location of the plant from which diverted in all cases in which 65 percent of more of a producer's milk is delivered to a minus 10-cent, zero, or plus 10-cent, zone is not persuasive. Location adjustments are intended to assure that milk produced in one part of the marketing area and needed in another location will be provided an economic incentive to move to where it is needed. If no movement that requires additional hauling expense occurs, location adjustments should not be necessary.

2. Reporting (Order 49)

A Hoosier proposal to eliminate from Order 49 a reporting requirement that handlers notify the market administrator of their intention to divert milk prior to doing so should be adopted. According to proponent witness, the notification requirement has not been enforced for many years. He also stated that such a reporting requirement would be cumbersome, if not impossible, to fulfill, and that the market administrator has no use for such data even if it were reported. No opposition to the proposal was received at the hearing, and its adoption was supported in the brief filed on behalf of NFO.

The provision proposed to be deleted appears to be not only unnecessary, but,

if it were enforced, a positive hindrance to the efficient and economical marketing of producer milk. Diversions of milk to nonpool plants apparently have become much more common and voluminous since the provision was adopted. Many diversions also would not be planned for with enough time to give prior notice to the market administrator. Other Federal milk orders operate well without such provisions, as the Indiana order apparently has for some time without it being enforced. Therefore, the requirement should be removed.

3. Classification

The portion of the multiple component pricing proposal that would have changed the classification of packaged fluid milk products in inventory at the end of a month from Class III to Class I does not need to be considered in this proceeding because the proposed change was included in the November 1991 recommended decision on issues considered at the national hearing held in the fall of 1990.

A proposal by New Paris Creamery to amend Order 49 to change the classification of milk used in infant formulas from Class II to Class III because of a difference in classification of the product between the Indiana and Southern Michigan orders also is not addressed in this decision. The November 1991 recommended decision on national hearing issues included uniform classification provisions for all Federal milk orders. Adoption of uniform classification should eliminate the problem addressed by the New Paris Creamery proposal.

4. Multiple Component Pricing (All Three Orders)

a. Protein Pricing

A proposal to incorporate a multiple component pricing plan in the Ohio Valley, Eastern Ohio-Western Pennsylvania, and Indiana Federal milk orders should be adopted, with some modifications. The pricing plan generally would be patterned after the multiple component pricing plan that has operated under the Great Basin milk order for several years. Producers would be paid on the basis of the pounds of milkfat and protein contained 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 milkfat, the protein used in Classes II and III, the skim milk used in Class I, and the hundredweight of total product used in Classes I and II.

The pricing plan recommended in this decision would vary from the initial protein pricing plan in the Great Basin order by using the percentage of protein contained in the milk included in the Minnesota-Wisconsin price survey rather than the marketwide average protein percentage, and by adjusting protein prices paid to producers and charged to handlers by the somatic cell count of the milk.

The proposal to incorporate multiple component pricing in Orders 33, 36 and 49 was proposed by Milk Marketing Incorporated (MMI), and Hoosier Milk Marketing Agency (Hoosier). The proponents' witness explained that in May of 1990 MMI marketed approximately 67 percent of the milk pooled on Order 33 with 1,988 producers and approximately 40 percent of the milk pooled on Order 36 with 2,020 producers. The witness explained that Hoosier consists of Associated Milk Producers, Inc. (AMPI) and MMI. These two cooperatives, through Hoosier, represent 1,475 producers whose milk is pooled on Order 49, and 65 percent of the producer milk pooled under that order.

Proponent witness explained that milk has been priced on the basis of butterfat and volume for many years. He stated that in recent years, however, demand for lowfat dairy products has changed the emphasis as to which fraction of the milk has the most value. For many years, he testified, the butterfat fraction had the most value and therefore was a major pricing factor in milk. However, with the popularity of lowfat products, the skim fraction has become the major factor of value in milk. Data introduced by the witness showed that since the 1960's butterfat has gone from 77 percent of the value of milk down to 32 percent of the value, with the skim showing a corresponding increase in the percentage of value in the milk. The witness went on to state that by pricing milk on the basis of its protein, as well as butterfat content, the producers would receive the pricing signal necessary to adjust to changes in the marketplace.

The proponents' representative presented several reasons for the implementation of multiple component pricing under Orders 33, 36, and 49. The first reason given by the witness was that these three orders should have mandatory multiple component pricing regulated by the Federal order system. The witness stated that although 77 percent of the Order 33 producers, 65 percent of the Order 36 producers, and 99 percent of the Order 49 producers were eligible for some form of multiple component pricing in May of 1989, the

multiple component pricing plans currently in effect vary in their payment criteria, resulting in disorderly marketing conditions in these three markets.

The witness explained that since proponents' plan would incorporate the pooling of the protein value, producers with above average protein would benefit. According to the witness, some milk is bypassing certain plants to receive multiple component pricing, thus increasing transportation costs and helping create a disorderly marketing condition. He stated that producers would benefit from having their milk shipped to the nearest plant rather than bypassing bottling plants and going to manufacturing plants.

The second reason given by the proponents' witness for implementing multiple component pricing was that the current pricing system does not properly reflect the value of the milk. The witness pointed out that the skim fraction of milk has gone from representing 25 percent of the value of milk during the 1960's to representing 65 percent of the value of milk at the present time. The witness stated that as a result the most valuable portion of the milk is not priced. Therefore, he concluded, the market does not send economic signals to the producer about the composition of the milk produced.

The third reason given by the proponents' witness for implementing multiple component pricing under the Federal orders is the growing interest by consumers in the nutritive value of their diets. The witness explained that consumers are becoming increasingly interested in the nutritive content of their dairy foods, while the present pricing system does not recognize the relative value of these components in milk. The witness pointed out that while the present system does not reward dairy farmers who produce milk containing more than average protein, which is valued by consumers, it does pay for additional butterfat, which is rejected by consumers. The witness continued by explaining that the proposed multiple component pricing plan would encourage producers to increase the content of milk components that are worth more, such as protein, in relation to the components of milk that are not worth as much, thus improving the milk to meet the demands of the marketplace.

The representative for the proponents explained that the proposed multiple component pricing plan is modeled from the Great Basin order, and would include protein as a component to be priced, in addition to the butterfat and

product pounds that are now used in determining producers' pay prices.

Proponent witness stated that the proposed multiple component pricing plan is modeled on the Great Basin order because the provisions of that order incorporate the current structure of the three orders for which the plan is proposed, and have been used successfully for several years. He stated further that the Great Basin order excludes adjustments to the Class I price, an important feature for maintaining uniformity in Class I handler costs. The witness also argued that the Great Basin order provides for multiple component pricing on Class II and Class III milk, where there is a demonstrable relationship between the components of milk and the yield of finished products.

The witness then explained the modifications of the Great Basin order's multiple component pricing plan proposed by proponents. The first modification addressed the computation of the protein price. Under the initial protein pricing plan of the Great Basin order, the handler protein price is computed by dividing the Class III skim price by the previous month's marketwide average protein percentage. According to the witness, use of a different marketwide protein test for each market would result in each market having a different protein price and, therefore, differing Class III prices between markets, leading to disorderly marketing conditions.

Proponent witness described five alternatives for determining the protein price, and said that the most preferred method would use formulas to compute a butterfat price and a protein price, probably based on the Chicago butter market and the Green Bay cheese exchange. However, the witness indicated, this type of change in pricing would not be practical now. All of the remaining alternatives for computing the protein prices would use the Class III skim price divided by one of several protein percentages. The witness stated that proponents prefer the method which would use the protein percentage of the milk received by plants included in the Minnesota-Wisconsin survey. According to the witness, use of this protein percentage under all three orders would result in the same handler protein price under the three orders, thus avoiding a potential source of market disorder. The protein price would then reflect more closely the value of protein contained in milk included in the M-W survey.

The witness also pointed out that by using the M-W protein percentage, producers will be able to increase the

protein content of their milk without reducing the protein price, a result which would occur when market average protein content is used. Another alternative suggested by the witness would be to have the Market Administrators of Orders 30 and 68 (for the Chicago and Upper Midwest marketing areas) test and report a protein percentage for the plants that are in Minnesota and Wisconsin and are pooled on those orders. A third alternative that the witness listed for determining the protein percentage was to have the department conduct a survey of plants in Minnesota and Wisconsin to determine the average protein content of their milk. This average would then be used to determine the handler protein price. The witness added that if the protein percentage from one of the above alternatives cannot be obtained, use of the current month's market average protein percentage would be acceptable.

Another modification of the Great Basin order advocated by proponents' witness was to include the Class II price differential in computing the producer protein price. The Great Basin order uses both the Class I price differential and the Class II price differential in computing the producers' weighted average differential price. In proposing this change, the witness stated there would be a Class II protein price as well as a Class III protein price. The witness said that this change would show the producer that the protein fraction of the producer's milk is worth something and would thus encourage producers to increase the protein content of their milk.

Another change from the Great Basin order proposed by proponents is the separate pricing of Class II and Class III milk used-to-produce manufactured products, and the other milk uses in these two classes. The proponents' proposal would price milk used to produce manufactured items on the basis of protein and butterfat, while the other Class II and Class III uses, such as inventory, shrinkage, and fluid cream products, would be priced as they are now; i.e., on the basis of skim and butterfat. The witness stated that this change is favored because non-used-to-produce items do not rely on the protein content of the milk for their value. Therefore, he said, handlers should not have to pay for protein that has no relationship to yield. The witness also advocated the inclusion of transfers and diversions to nonpool plants under the multiple component pricing plan.

Proponents' representative explained that the final modification proponents desired to make in the Great Basin order

to adapt its use to the three orders under consideration is the inclusion of somatic cells in the computation of handler protein prices and producer protein prices. The witness characterized this difference as pricing protein on its "true value". The witness said that the industry recognizes somatic cells as a factor in the "availability" of protein for use by handlers, and therefore as affecting the value of protein to handlers. The witness continued by saying that producers would receive the proper return for their milk by including somatic cells in the computation of each producer's pay price. The pricing of milk according to its somatic cell content will be discussed in detail later in this decision.

A witness for National All-Jersey, Inc., testifying in support of proponents' multiple component pricing plan, stated that including multiple component pricing in these three orders will provide an important mechanism for enhancing the efficiency of milk production and marketing. The witness pointed out that not only will handlers and producers benefit from multiple component pricing, but consumers also will benefit.

The witness explained that handlers would benefit because they would be required to account for the milk components that give milk value. With multiple component pricing, handlers would know the protein content of the milk they are receiving and would consequently be able to do a better job of using the protein to yield the best return. The witness compared accounting for protein to the present accounting for butterfat. The witness went on to explain that handlers do not want to pay for something that they don't receive, and that with the proposed multiple component pricing plan, they would pay only for what they get.

Producers would benefit, explained the witness, because they would be rewarded if they produce the higher-protein milk that is demanded by the marketplace, in contrast to the present system in which there is no reward for higher-protein milk. Also, he said, since under the proposed multiple component pricing plan the producer would be paid for pounds of protein, pounds of butterfat, and total product pounds, the producer could clearly determine what component of his milk is giving the greatest return and therefore what component to improve in his herd. The witness also pointed out that since the product pounds will be valued at the weighted average differential the producer can see what value

participation in the pool contributes to his return.

A representative of National Farmers Organization, a dairy farmer cooperative, testified in support of the proposed multiple component pricing plan. The witness explained that NFO supports multiple component pricing because producers will be rewarded for supplying the market with the milk components that the marketplace demands. The witness went on to explain that NFO supports the proposed pricing plan because, unlike the initial Great Basin multiple component pricing plan, the producer protein price would not be reduced as the marketwide percentage of protein increases.

The NFO witness also expressed support for the use of protein rather than nonfat solids in the proposed multiple component pricing plan. He supported the use of protein rather than nonfat solids because protein is the component most demanded by handlers in the marketplace, and because producers are familiar with protein levels in their herds due to protein testing by the Dairy Herd Improvement Association (DHIA) and by USDA sire summaries. The NFO witness did, however, express concern over the use of a producer protein price that may cause a decline in income for 50 percent of the producers. The witness suggested that a neutral protein range be adopted with a plus adjustment for protein percentages above the neutral range and negative adjustments for protein percentages below the neutral range.

A representative of Dairyalea Cooperative, Inc., testified that Dairyalea has approximately 2,300 members, with the milk of one hundred and twenty of these producers pooled on Order 36. The Dairyalea representative stated that at Dairyalea's last annual meeting a resolution was passed favoring Federal order amendments that encourage the use of protein or nonfat solids as part of the pricing system. The witness continued by saying that the time has come for protein pricing, particularly since the value of butterfat has declined substantially relative to the value of the protein or nonfat fraction of milk solids.

A witness for Kraft USA testified in favor of the multiple component pricing proposal. The witness expressed particular support for the use of the M-W protein average in computing the handler protein price. The Kraft witness explained that by using the M-W protein average rather than a market average, handlers' cost of protein from market to market would be equal, as it is for butterfat. This would allow handlers from areas with varying protein levels to compete on an equal price basis.

According to the witness, this would not be the case when the market average protein percentages are used to compute the handler protein price.

The multiple component pricing proposal was also supported by a representative of National All-Jersey Inc., and the American Jersey Cattle Club. The witness explained that National All-Jersey is a national dairy farmer organization affiliated with the American Jersey Cattle Club, a breed registry organization for owners of Jersey cattle that provides marketing services to its members. The witness stated that the two organizations have 796 members in Indiana, Ohio, and Pennsylvania. He explained that a milk pricing system should give producers the incentive to produce the components demanded by consumers, be of value to processors, and be fair to producers. The witness testified that the present pricing system does not accomplish this function, while the proposed multiple component pricing plan would. The witness said that the present pricing system, because it does not account for the protein or solids in milk, encourages a producer to produce water for which he receives the same return as he does for the solids. By accounting for and pricing protein, the witness stated, the multiple component pricing plan would encourage producers to manage their herds to obtain the greatest return by increasing their protein levels. The witness continued by saying that the production tools are in place to increase protein levels, even to the extent of increasing protein while decreasing butterfat. All that is lacking, he said, is the marketing incentive to do so, and incentives will be provided with the implementation of multiple component pricing.

The multiple component pricing proposal was supported in a post-hearing brief filed on behalf of Brewster Dairy, a proprietary supply plant operator regulated under Order 36. The Brewster brief favored adoption of the proposal on the basis that the proposed provisions providing a uniform price per pound for protein and an economic adjustment for somatic cells are needed.

A brief filed on behalf of the Dairy Industry Association of Western Pennsylvania opposed adoption of the multiple component pricing plan on the basis that the record of the hearing supports a national multiple component pricing plan with consistency between orders. The Association's brief states that over-order premiums already are substantial and significant enough to provide incentives and send signals for producers to increase the protein content of their milk production until

uniform multiple component pricing provisions can be adopted nationally. The brief acknowledged the benefits from and demand for higher protein content and lower somatic cell counts demonstrated in the hearing record.

Multiple component pricing should be included in the amended orders, with pricing on the basis of butterfat and protein. The record shows that a large percentage of producers whose milk is pooled under the three orders already are eligible for or receive some form of multiple component pricing, and that nearly all of these component pricing plans use protein as a pricing component. The record also indicates, however, that different handlers have differing protein premium payment programs, resulting in nonuniform bases of payments to producers. Such differing bases for payment may cause, and according to proponents has caused, disorderly conditions in the procurement of milk supplies by competing handlers. In addition, adoption of multiple component pricing will allow the order to recognize the additional value in milk with a higher-than-average protein content by incorporating such pricing within the order.

The hearing evidence leaves no question that payment for milk on the basis of its protein content can be justified on the criterion of economic value. Milk containing a higher percentage of protein will result in greater yields of most manufactured products than milk with a lower protein test. Handlers receiving milk that will result in greater volumes of finished products such as cheese or 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 product deserves to be paid more for it than a dairy farmer producing the same volume of milk that results in less product yield.

Pricing milk on the basis of its protein content also meets the criteria of measurability, intrinsic value, and variability. The evidence in the record shows that protein can be easily measured and, in fact, that the variability in measurement may be less than the variability in butterfat testing because protein does not separate as butterfat does. Second, the record evidence shows that protein has value to the manufacturing sector in the form of improved product yield and product structure. The value to the fluid sector was not quantified in the hearing record; however, testimony indicated

some benefit to the fluid sector from higher-protein milk, resulting in a more nutritional product. The criterion of variability is necessary to justify pricing a component separately from the product in which it is contained. In the case of protein in milk the record shows that the level of protein varies from season to season, region to region, and farm to farm. In view of its economic value in dairy products, its widespread use as a pricing component in the three markets, and its qualification under the three criteria above, protein appears to be the appropriate component for pricing milk in these orders.

Pennsylvania Farmers Union and Farmers Union Milk Producers Association (Farmers Union) filed comments objecting to the proposed component pricing formula on the basis that it would result in reduced returns to low-protein producers and drive many producers out of business. Pennsylvania Farmers Union's comments stated that it is difficult to reverse a half-century of breeding for butterfat, and expressed the fear that the proposed pricing plan would result in an instant penalty for butterfat production.

Although the component pricing plan adopted in this decision will reduce returns to producers whose milk contains less than average percentages of protein, that fact does not provide a basis for failing to adopt a multiple component pricing plan. It is not unfair to pay producers according to the actual value of their milk used in dairy products. In fact, the present method of payment could be considered inequitable to the extent producers producing higher-than-average levels of protein are not compensated for the full value of their milk.

The price for protein should be based on the Minnesota-Wisconsin price and the protein content of the milk included in the Minnesota-Wisconsin price series. The handler protein price should be computed by subtracting from the Minnesota-Wisconsin price for the month the butterfat price multiplied by 3.5, and dividing the result by the average protein content of the milk included in the determination of the Minnesota-Wisconsin price.

Proponents presented several alternatives for computing the handler protein price because it was not known at the time of the hearing whether or not the protein content of the Minnesota-Wisconsin milk would be available to compute the handler protein price. Since the hearing, however, the protein content of the milk used for the Minnesota-Wisconsin price has begun to be collected and reported for the month

preceding the month for which the M-W price is announced. This data can be adjusted for the current month using historical data collected by the market administrators of the Upper Midwest and Chicago Regional milk orders. With the availability of this information, the other alternatives are no longer relevant. Not only did the testimony strongly favor using the protein content of the Minnesota-Wisconsin milk to determine the handler protein price, but as multiple component pricing becomes a more common feature of Federal milk orders, it will be necessary that a standard price for protein be used.

The proponents' proposal to price Class II and Class III used-to-produce items separately from Class II and Class III other uses should not be included in the amended orders. This proposal would result in the three orders included in this proceeding having five classes of utilization as well as different protein prices for Class II and Class III. At the present time, almost every Federal order has a three-class market, with the industry moving to more uniform classification rather than away from it. The November 1991 recommended decision on the national Federal milk order hearing includes provisions for uniform classification in all of the federal orders. Adoption of proponents' modification would compound problems of interorder differences in regulation. At the same time, there is some question about whether only used-to-produce items are favorably affected by higher protein content. Testimony at the hearing indicated that fluid cream products benefit from higher protein levels, and therefore should be included in the protein pricing of Class II items. The remaining products that make up the proposed "other uses" portion of Class II and III are a very small percentage of the milk pooled and would therefore not affect the producer protein price. In fact, on the basis of pool data from the hearing record, this particular portion of the multiple component pricing proposal would have no effect on the weighted average differential and producer protein price or handlers' cost of milk.

Kroger, Superior Dairy, and Dairy Industry Association of Western Pennsylvania (on behalf of the Association, Superior Dairy, Inc., and United Dairy of Ohio, Inc.) filed comments opposing the application of multiple component pricing to all Class II and Class III milk. The comments argued that there is no economic justification for incorporating a protein pricing formula on uses of milk which are not affected by protein content.

Comments on behalf of Kroger explained that some used-to-produce Class II products such as frozen desserts and dips will not derive an economic benefit by incorporating multiple component pricing in their cost structure because the price or product yield of none of these items are influenced by the amount of protein in the raw milk used in their manufacture. Kroger complained that the proposed pricing system potentially would make it impossible to recover the cost of these products compared to competitors regulated in markets where component pricing does not exist. Kroger claimed that the proposed decision will create inequitable and uncompetitive Class II and Class III market conditions for processors regulated in Orders 33 and 49.

Kroger and the Dairy Industry Association of Western Pennsylvania, (the Association) stated that the argument presented by the Department of establishing uniformity among Federal Orders is unsubstantiated. Kroger posed the question of why the Department granted Class III-A classification to some and not all federal orders if the Department is as determined to establish uniform classification within the order system as the national hearing decision indicates. The Association explained that many Federal Orders do not have a multiple component pricing system and that the proposed decision is breaking new ground with regard to the establishment of such pricing.

The Association claimed that the statement that the proposal would create five classes of milk gives a misleading impression that if the proposal were adopted the orders would not be compatible with the more general three-class structure. The organization stated that the used-to-produce and non-used-to-produce categories are merely subcategories of the existing Classes II and III, and that no products were shifted between those classifications. In addition, the organization stated that there would be no difficulty in combining the subcategories in Classes II and III to give totals for those classes comparable to other orders when required.

Kroger proposed that the originally proposed language, which priced only "used-to-produce" Class II and III manufactured items, be adopted. Kroger stated that such a provision would assure handlers regulated under Orders 33 and 49 that costs of Class II and III items whose price, cost, and yield are determined by components other than protein would be similar to their competition in other orders.

The Association claimed that increased protein content does not add any measurable benefit to most fluid cream products on the market. However, the Association's comments stated that if on the basis of the testimony the Secretary finds that fluid cream does directly benefit from higher protein levels, fluid cream products should be shifted to a used-to-produce category rather than have the orders fail to differentiate between used-to-produce and other uses.

Division of Class II and III into "used-to-produce" and "non-used-to-produce" categories for the purpose of pricing differences is an unnecessary complication. Most handlers' receipts will not differ greatly from the average protein content, as the milk of many producers, when commingled, will tend toward an average protein test. In addition, the value of "used-to-produce" milk as determined by Class prices cannot differ materially from the value of such milk as determined by component prices since the component prices add up to the Class III price. Further, according to expert testimony, the protein content of milk affects the ability of such products as whipping cream and ice cream mix to hold air, affecting the quality or yield of both products. The inclusion of milk used in these products, combined with Class I classification of packaged fluid milk products in ending inventory, would result in very little milk to be priced in the "non-used-to-produce" category.

The experience of using pricing systems similar to the one adopted in this decision in the Great Basin marketing area since April 1988 and in the Middle Atlantic marketing area since January 1992 indicates no dissatisfaction with pricing all Class II and III milk on the basis of its components. In fact, although a hearing was held in August 1990 to consider proposed amendments to the Great Basin order that included several proposals to adjust details of the Great Basin protein pricing procedure, no handlers or producer groups whose milk is regulated under that order proposed that any changes be made in pricing all of the milk used in Classes II and III on the basis of its components.

The argument that protein used in Class II should have a higher price than protein used in Class III was not supported by the evidence at the hearing. The testimony at the hearing clearly showed that protein has value in used-to-produce products in both Class II and Class III, but the testimony did not establish any additional value or additional contribution of the protein used in Class II products versus protein

used in Class III products. Therefore, the added value of Class II products should be represented entirely by the weighted average differential rather than by a Class II protein price.

Comments filed by MMI expressed concern that the protein content of bulk milk, and its somatic cell content, need to be followed throughout the accounting process in order to be properly priced. In addition, MMI stated, the protein content of milk transferred to other handlers should be accounted for.

The order language accompanying this decision requires handlers to report the butterfat and protein content of milk transferred and diverted to other plants. Beyond this requirement, it is not feasible or necessary to follow protein content and somatic cell counts through processing within the plant. In addition to the unlikelihood that milk will be segregated for further use after receipt at a plant, there is no indication in the record of this proceeding that protein or somatic cells are easily separable from the skim milk in which they are contained. Requiring such accounting, and the testing necessary to carry it out, would be unnecessarily burdensome for handlers. Therefore, the orders should operate under the assumption that "protein follows skim", prorating protein to the uses of the skim milk in which it is contained.

Comments filed on behalf of the Milk Industry Foundation (MIF) opposed the application of multiple component pricing to Class I milk, stating that handlers' payments for Class I milk should not be based on the protein content of the milk. The pricing plan adopted in this decision does not intend, and should not result in, adjustments for protein content to handlers' value of milk used in Class I.

b. Somatic Cell Adjustment

The value of milk should reflect the level of somatic cells contained in that milk. The change in value should be made by adjusting the protein price paid by handlers for Class II and Class III milk, and the protein price paid to producers, for the somatic cell content of the milk.

An expert witness for proponents of the multiple component pricing proposal testified that a somatic cell count is a measure of the concentration of white blood cells in milk. According to the witness, these cells are present in the milk as an immune response to a bacterial infection of a cow's udder. The white blood cells attack and destroy the bacteria and, in the process, contribute to the damage the bacteria has done in the secretory system. They also release

enzymes that not only attack the bacteria, but also affect the milk. Besides causing loss of quality of the milk, the somatic cells also may cause a decrease in production in the affected animal and, in very severe cases, death of the animal.

The witness continued by saying that the effect of somatic cells on milk occurs primarily in the udder of the cow where conditions are favorable for the development of bacteria and the activity of the somatic cells. Once the milk has been removed from the cow and placed under correct handling conditions, stored at or below 4.4 degrees Celsius (40 degrees Fahrenheit), the activity of the cells is reduced and further deterioration of the milk is minimal. Some of the enzymes, however, are not destroyed during pasteurization and therefore may continue to affect milk quality. The expert witness testified that somatic cells cause a breakdown of fat with a resultant release of free fatty acids. These fatty acids cause a rancidity and an off-flavor in dairy products.

Proponents' expert witness testified that the effect of somatic cells on manufactured products is attributed to the enzymes released by the somatic cells. These enzymes attack the casein in the milk and break the casein down into shorter chain proteins that are then lost in the whey during the cheese-making process. The general result is that under identical conditions with milk of equal protein tests, milk with a higher somatic cell count will yield less cheese due to lower casein levels than will milk with a lower somatic cell count. The witness also explained that somatic cell levels affect the final moisture content of the cheese and the activity of the cheese starter. According to the witness this reduction in the functional ability of protein to result in a high-quality manufactured product is not limited to cheese. He stated that any manufactured product that relies on protein to give it structure or form is also affected by degradation of the protein by somatic cells.

Several proponent witnesses testifying on the issue of somatic cells stated that as the number of somatic cells increases, the quality of milk, even that used in fluid products, decreases. A witness for Brewster Dairy testified that Brewster's fluid customers are willing to pay a premium for low somatic cell count milk because of its extended shelf life. Another witness, representing Dean Foods, stated that lowering the somatic cell counts helps bottlers by increasing the quality of the milk, consequently increasing the shelf life of the fluid products.

The quantitative effect of various somatic cell levels on the yield of cheese was discussed at great length at the hearing because this measurement is the basis for the somatic cell differential levels included in the protein payment proposal. Proponents' witness indicated that commingled milk shows a more linear relationship between somatic cell counts and cheese yield than does milk from individual cows, and that milk from individual udder quarters will show more variability from a linear relationship of the two factors than milk from individual cows. However, he stated, the relationship between changes in somatic cell counts and cheese yields is not linear, even with commingled milk. Proponents' witness explained that there is a sudden decrease in cheese yield of about one percent as the somatic cell count increases to approximately 100,000. As the somatic cell count increases from 100,000 to 1,300,000, he testified, the decline in cheese yield may be an additional one to two percent depending on milk handling conditions. The witness testified that there is a three- to four-percent decline in cheese yield as the somatic cell count goes from 100,000 to 1,000,000. Although there is an apparent discrepancy between one of the studies introduced and the testimony of the proponent witness, both show a relationship between somatic cell levels and cheese yields.

The witness went on to discuss research that showed cheese yield decreasing by approximately five percent as somatic cell counts increased from 100,000 to 500,000. The study showed that as somatic cell counts increased from 500,000 to 1,000,000, cheese yields decreased an additional 3.7 percent for a total decrease in yield of 8.7 percent. The witness pointed out that the researcher identified a loss in cheese yield of .045 kg per 45.36 kg of milk for every 100,000 increase in somatic cell counts. This translates to a 1/10th of one percent decrease in cheese yield per every 100,000 increase in somatic cells.

A witness for Kraft USA summarized the results of the three studies received into evidence by concluding that the studies showed an average .07 pound decrease in cheese yield for every 100,000 increase in somatic cell count. A representative of Brewster Dairy stated that Brewster uses as a rule of thumb a 1/10th of one pound change in cheese yield for each 100,000 change in the somatic cell count.

A witness for MMI explained that the five percent figure used in the multiple component pricing proposal to compute the somatic cell differential was derived

from the conclusion that as somatic cell counts increase from 100,000 to 1,000,000, cheese yields decline by one pound. The witness stated that this one pound decline represented a ten percent factor of the cheese price and that the proposal was intended to represent one-half of the reduction in cheese yield attributable to somatic cells. The proposed ten percent factor represents the incremental change of one tenth of one pound of cheese and not the percentage change in the cheese yield if the yield changed from 10 pounds of cheese per 100 pounds of milk to 9.9 pounds of cheese per 100 pounds of milk.

A witness for MMI stated that the neutral range in the somatic cell differential was chosen because that is the range into which MMI's weighted average somatic cell count falls. Proponents proposed that producers' pay prices increase with somatic cell counts below the neutral range and decrease with somatic cell counts above the neutral range. Proponent witness explained the use of 200,000 cells as the lowest category by stating that there is no significant effect on cheese yields as somatic cell counts decline below 200,000. A witness for Kraft USA stated that the 200,000 somatic cell level was used as the minimum category because McDonald College of McGill University considers somatic cell counts below 200,000 to be from a healthy cow.

A witness for Kraft USA, testifying as a proponent, explained that somatic cell testing consists of counting the number of cells in a specified size sample of milk, and described two procedures used for counting somatic cells: the direct microscopic somatic cell count (DMSCC) and the optical somatic cell count (OSCC). The DMSCC is a manual microscope counting method while the OSCC is an electronic method.

The Kraft witness explained that there are two different machines that use different techniques for determining somatic cell levels. The Fossomatic machine uses a dye to stain somatic cell nuclei and then counts the stained cells. The Coulter counter counts particles of a certain size. A witness for proponents observed that the Fossomatic was the more commonly used machine in the dairy industry. It was also pointed out that both machines must be calibrated against a known standard, and that in the case of somatic cell testing, the standard is the DMSCC method.

A witness for MMI testified that both MMI and the Ohio DHIA use the Fossomatic machine for their somatic cell testing. The witness stated that a Fossomatic machine costs around \$65,000, while another proponent

witness put the cost of OSCC machines between \$38,000 and \$195,000, depending on the options included, as compared to the \$2,000 to \$4,000 for the DMSCC.

The proponent witness noted that, as with any laboratory procedure, employee training and skill are critical to the results of the procedure. The record states that the coefficient of variation for somatic cell testing should be below 5 to 7.5 percent while the coefficient of variation for butterfat and protein testing is approximately one half of one percent. However, according to proponents' expert witness, the variability in testing is randomly distributed and therefore would not consistently bias a producer's pay price one way or another. The witness also testified that since there are many industry payment plans using somatic cells as part of their payment criteria there is an industry standard for somatic cell testing that the industry trusts and uses.

For somatic cell counts to be used for determining payments to producers, the level of somatic cells must affect the value of the milk to the user. The hearing record contains substantial testimony to the effect that as somatic cell counts increase the functional value of the milk decreases. The record shows that this change in functional value affects all dairy products, from fluid milk to hard products. In fact, several witnesses testified that high somatic cell counts reduce the quality and shelf life of fluid milk products. The record also shows that somatic cell levels have an effect on the molecular structure of soft manufactured products, including the ability of cream to whip properly. In the manufacture of hard products, record evidence shows that the yield of cheese is directly related to the level of somatic cells in milk.

The recommended decision in this proceeding proposed that the producer protein price for all milk be adjusted for somatic cell count outside the pool, as is currently the case with butterfat. Although there was little opposition to the incorporation under the order of some form of somatic cell adjustment, a number of exceptions were filed in response to the recommended decision on this issue. The exceptions focused primarily on the effect the proposed somatic cell adjustment would have on fluid milk handlers and the basis for making somatic cell adjustments applicable to all milk. In addition some handlers, even those who favored applying such an adjustment to all milk, considered the proposed neutral zone of 400,000-500,000 too high.

Many of the Class I handlers in the three marketing areas argued that the application of price adjustments on all milk for somatic cell count was not proposed in the hearing notice or in testimony at the hearing. These commentators stated that the hearing record contains no evidence of any measurable economic benefit to fluid milk handlers from reduced levels of somatic cells, and that any testimony supporting such adjustment was casual and incidental.

Some of the Class I handlers complained that the recommended adjustments, by being based on the cheese price, would affect the advance notice feature of Class I pricing because the cheese price is not available when the Class I price is announced. Consequently, they stated, the somatic cell adjustment would have to be estimated.

Several of the Class I handlers also stated that they would be unable to recover the benefit of low somatic cell count milk in the marketplace. They argued that adoption of the recommended provisions would give fluid milk handlers a strong economic incentive to procure low-quality milk as a result of the increased cost of high-quality milk. According to these exceptors, the somatic cell adjustment would increase their cost of milk and make them uncompetitive with handlers regulated under other orders.

A number of exceptors argued that a neutral range of 400,000-500,000 somatic cells is too high, with one comment suggesting 250,000-300,000 as a more appropriate range, and others advocating 300,000-400,000. Several comments observed that the new Pasteurized Milk Ordinance Grade A standard for somatic cells, to be effective in 1993, will be reduced from 1,000,000 to 750,000 somatic cells, and argued that when observations greater than 750,000 are eliminated, the average somatic cell count will decrease. Another comment stated that 40-50 percent of producers' milk falls within the 200,000-400,000 range.

Two comments filed by a veterinarian/dairy farmer contradicted evidence about somatic cell testing in the hearing record and asserted that testing for somatic cells suffers from inaccuracy, variability and lack of repeatability. He argued that connecting payment for protein with somatic cell counts would result in penalties for high-protein milk that enhances cheese yield. The veterinarian/dairy farmer and comments filed by the Milk Foundation of Indiana urged that a limit be established on the amount of somatic

cell adjustments, such as 15 cents or 12-18 cents.

Several comments favoring adoption of the recommended decision were submitted, including comments filed on behalf of Hoosier and MMI. Hoosier characterized the testimony supporting the application of somatic cell adjustments to all milk as substantial. In addition, National All-Jersey urged the application of protein pricing, as well as somatic cell adjustments, to all milk.

The effect of somatic cell adjustments on the advance nature of Class I prices could be expected to be minimal. The somatic cell adjustments are a very small portion of the cheese price, and any changes from month to month would be correspondingly small in relation to changes in the cheese price. In addition, the biggest factor in Class I price movements is the amount of change in the Minnesota-Wisconsin price, which can be expected on average to represent 10 times the change in the cheese price.

Regarding assertions that somatic cell adjustments would increase Class I handlers' cost of milk significantly, it is unlikely that any handler's total milk receipts would vary greatly from the market's average somatic cell count. It is also probable that application of somatic cell adjustments to Class II and III milk, but not to Class I, will result in Class I handlers receiving lower-quality milk from suppliers without the payment of some additional premium.

Although the record contains significant testimony relating the somatic cell count of milk to the quality, including flavor and shelf-life, of fluid milk and cream products, there was insufficient opportunity for opponents to counter the testimony supporting such a modification of proponents' proposal. The provisions included in this decision adjust handlers' costs for the protein in milk used in Classes II and III for somatic cell count and the protein prices paid to producers for all of their milk. The aspect of the recommended decision that would have included somatic cell adjustments by handlers on all protein in producer milk, including that used in Class I, has been changed.

In addition, the neutral range proposed and recommended at 400,000-500,000 is reduced to 301,000-400,000. Although the average somatic cell count for the period for which MMI entered statistics did fall within the 400,000-500,000 range, a closer inspection of the statistics shows that the median somatic cell count is significantly lower. In other words, the somatic cell count of over half of the producer milk for which MMI had statistics was generally in the

lower half of the 301,000–400,000 increment, and sometimes just under 300,000. The average in this case clearly is substantially influenced by several observations in the 1–2 million somatic cell count range.

In this situation, an attempt to make the somatic cell adjustment neutral for "average" producer milk requires using the median somatic cell count instead of the average. In addition, because of the reduction in the maximum permissible somatic cell count, 750,000 and over will become the maximum increment for which protein prices will be adjusted for somatic cell content. Because of differences between the market administrators and health departments in the number of leucocyte (somatic cell) tests taken in a given period of time, it is entirely possible that some Grade A producers may have an average somatic cell count of 750,000 or more for a month without losing Grade A status.

A further modification of the recommended decision is the breakdown of somatic cell counts into smaller increments for adjustment purposes. Increments of 50,000 will assure producers that if slight testing inaccuracies (which are greater in the case of somatic cells than for butterfat or protein) cause their protein price to be adjusted to the next lower level, that adjustment will not represent the entire value of a 100,000 increment of somatic cell count.

Since the value of milk has been shown to be affected by the level of somatic cells, appropriate adjustments must be determined to apply to the various levels of somatic cells. These adjustments will then be used to adjust handlers' values of protein in Classes II and III, and the protein prices paid to individual producers. The somatic cell adjustment to handlers' value of milk will be computed by multiplying the

appropriate constant for each handler's weighted average somatic cell count by the monthly average 40-pound block cheese price at the National Cheese Exchange as published monthly by the Dairy Division. The resulting somatic cell adjustment on milk used in Class II and Class III will be added or subtracted from the protein price paid by each handler.

In computing the producer protein price, negative somatic cell adjustments will be added to, and positive adjustments subtracted from, the total value of handler protein and Class I skim milk, with the result divided by the pounds of producer protein in the pool. Because of the necessity of pooling the somatic cell adjustments in order to avoid affecting the Class I price of milk to handlers, it will be necessary for the somatic cell counts for all producer milk to be reported at pool time.

The somatic cell adjustment to be used in determining protein prices paid to handlers and producers is derived from the reduction in cheese yield as the somatic cell level goes from zero to 1,000,000, converted to a value per pound of protein. The evidence contained in the hearing record shows that as somatic cells increase from 100,000 to 1,000,000 cheese yield declines anywhere from three percent to nine percent, with a substantial amount of this decline occurring somewhat below 200,000 somatic cells and above 900,000 somatic cells. Since the record clearly shows that the relationship between cheese yield and somatic cell count is not linear, the relationship adopted in this decision between the somatic cell adjustment and the somatic cell count is not linear, but reflects the proportional change in cheese yields as the somatic cell level changes.

The constant to be used was computed by dividing the change in the cheese yields attributable to changes in

somatic cell counts by a representative protein test of producer milk (3.2%). As proposed, the adjustment to the producer protein price for somatic cell content would be computed by dividing the product of the cheese price and a factor, which varied with the somatic cell level, by the average protein percent used in calculating the handler protein price. The proposed factors varied from .15 for a somatic cell count below 200,000 to -.30 for a somatic cell count above 1,000,000. The proposed factors changed by .05 for every 100,000 change in somatic cells, with a neutral range of 400,000 to 500,000 somatic cells. The factors contained in the proposal were based on the reduction in cheese yield associated with varying somatic cell counts, assuming a linear relationship between cheese yields and somatic cell counts.

Because the reduction in cheese yield with increasing somatic cells is not linear, the factors to be used in adjusting handler and producer protein prices for somatic cell content are revised from the proposal, as shown in Table 1. Dividing these factors by a standard protein content of 3.2 yields the constants shown in Table 1 to be used for computing the somatic cell adjustment. Use of a constant substantially simplifies the computation of the somatic cell adjustment without changing the corresponding value. This result occurs because the protein percentage must change by a considerable amount before the adjustment will change. Therefore, the somatic cell adjustment will be calculated by multiplying the constant corresponding to each somatic cell count interval by the average price of 40-pound block cheese at the National Cheese Exchange as reported monthly by the Dairy Division.

TABLE 1.—FACTORS AND CONSTANTS TO BE USED IN COMPUTING THE SOMATIC CELL ADJUSTMENT

Somatic cell counts	Factors	Constants for computing the somatic cell adjustment
1 to 50,000	.300	.09375
51,000 to 100,000	.200	.062500
101,000 to 150,000	.150	.046875
151,000 to 200,000	.100	.031250
201,000 to 250,000	.050	.015625
251,000 to 300,000	.025	.0078125
301,000 to 350,000	.000	.000000
351,000 to 400,000	.000	.000000
401,000 to 450,000	-.025	-.0078125
451,000 to 500,000	-.050	-.015625
501,000 to 550,000	-.075	-.0234375
551,000 to 600,000	-.100	-.031250
601,000 to 650,000	-.125	-.0390625

TABLE 1.—FACTORS AND CONSTANTS TO BE USED IN COMPUTING THE SOMATIC CELL ADJUSTMENT—Continued

Somatic cell counts	Factors	Constants for computing the somatic cell adjustment
651,000 to 700,000	-.150	-.046875
701,000 to 750,000	-.200	-.062500
751,000 and above	-.250	-.078125

In an ex parte communication received after the hearing, a veterinarian from Ohio expressed opposition to the inclusion of somatic cell adjustments in the multiple component pricing plan. His opposition stemmed from the variability in somatic cell testing that he had seen in his practice. His major complaint was with the accuracy of testing when the Coulter Counter is used for somatic cell testing.

As specified in the Agricultural Marketing Agreement Act of 1937, one of the functions of the market administrator is "Providing * * * for the verification of weights, sampling, and testing of milk purchased from producers." Since the market administrator will now be verifying the sampling and testing of milk for somatic cells, the variation in somatic cell levels due to testing should be minimized much as differences in butterfat tests due to testing variations were minimized when the Federal milk order program was first instituted. The concern expressed in the ex parte communication over the accuracy of the Coulter Counter is, perhaps, relevant in the current situation in which producer payments are affected by somatic cell counts only outside the Federal order. However, the Coulter Counter testing method is not one of the methods approved by the American Association of Analytical Chemists (AOAC) for determining somatic cell content, and is not likely to be deemed acceptable for determining producer payments under the Federal order. (Official Notice is taken of the publication "Standard Methods for the Examination of Dairy Products"; 15th Edition; Gary H. Richardson, Ph.D., Editor; American Public Health Association; 1985).

In the brief filed on behalf of NFO, the cooperative objected to the inclusion of somatic cells in the multiple component pricing plan. The brief contained four arguments against the inclusion of somatic cell adjustments to producer payments: (1) somatic cells are not part of the milk, and therefore are not subject to price differentials under the Agricultural Marketing Agreement Act in section 8c(5) 7 U.S.C. 608c(5), (2) somatic cells are a product of disease

and subject to wide fluctuations that could lead to inaccurate pricing unless every load is tested, (3) under the proposal, Class I handlers would not have to pay for somatic cells even though the hearing record showed that somatic cell levels are important to such handlers, and (4) the somatic cell adjustment contained in the multiple component pricing proposal uses a linear price reduction while the evidence in the hearing record indicated that the relationship between somatic cell levels and the value of milk to handlers is non-linear.

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." Because the record of this hearing shows that the presence of somatic cells directly affects the quality of milk and that the level of somatic cells in producer milk affects the grade of the milk in that somatic cell counts above a certain level will result in loss of a producer's Grade A permit, the argument that somatic cells can not be used as a criteria for adjusting a producer's pay price is not valid.

The contention that somatic cell counts have wider fluctuations than butterfat or protein tests is apparently valid. However, the hearing record does not contain enough evidence that the variability in testing outweighs the benefits of including somatic cell counts in the multiple component pricing plan.

Point numbers three and four of NFO's objections to including somatic cells in the multiple component pricing plan are discussed earlier in this section of this decision.

c. Other changes

With the inclusion of multiple component pricing in the three orders affected by this decision, certain conforming changes need to be made in these orders to implement this decision. Since protein will now be priced under the three orders included in this decision, each handler will need to include the amount of milk protein and somatic cells contained in total producer receipts, including protein and somatic cells contained in producer

milk diverted to other plants, with its report of receipts and utilization. As in the Great Basin order, the assumption will be made that the protein is uniformly contained in the skim portion of the milk and may not be separated easily. Therefore, the protein will follow the skim milk through the allocation process and be allocated proportionately with the skim milk. This allocation procedure means that handlers will not have to report the protein content of milk transferred to other handlers. For handlers filing payroll reports with the market administrator, the milk protein content and the average somatic cell count of each producer's milk will be included on the payroll report in addition to the information currently reported to the market administrator on such reports.

To properly price the components under the amended orders, several price computations must be defined. These are the skim milk price, the butterfat price, and the protein price. The skim milk price per hundredweight will be determined by subtracting the butterfat differential multiplied by 35 from the Class III price. The butterfat price per pound will be determined by adding the skim milk price divided by 100 to the butterfat differential multiplied by 10. The handler protein price per pound will be determined by subtracting the butterfat price per pound, multiplied by 3.5, from the Class III price and dividing the result by the average protein content of milk used in obtaining the basic formula price (the Minnesota-Wisconsin price). Since the proposed skim milk prices, butterfat prices, and protein prices for Class I and Class II are not specifically needed to determine the weighted average differential or the producer protein price, these prices are not defined in this decision.

Two separate marketwide pools will be used to determine the amount that producers will be paid for the milk, and the protein contained in the milk, that they deliver. The first marketwide pool will determine the weighted average differential, while the second marketwide pool will determine the producer protein price. The weighted average differential is the additional

value of the Class I and Class II milk in the pool and will be paid on all producer milk. The producer protein price is determined by the amount of protein used in Class II and Class III and the amount of skim milk used in Class I. In determining payments to producers, the producer protein price will be adjusted for each producer's somatic cell count, and be paid on a per pound of protein basis.

The weighted average differential is determined by computing, for each handler, the differential value of the product pounds used in Class I and Class II, and then adding or subtracting, as is appropriate, the value of such items as inventory reclassification, shrinkage or coverage, receipts of other source milk allocated to Class I, receipts from unregulated supply plants, and location adjustments. The above values are then combined for all handlers and the value of producer location adjustments and one-half the unobligated balance in the producer settlement fund are added. The resulting value is then divided by the total pounds of producer milk in the pool and an amount not less than four cents or more than five cents will be subtracted to arrive at the weighted average differential for the zero zone.

The producer protein price is determined by combining, for all handlers, the value of the pounds of skim milk allocated to Class I at the skim milk price with the value of protein contained in the skim milk allocated to Class II and Class III at the handler protein price adjusted for the average somatic cell count of the handler's receipts. The resulting total is modified to include somatic cell adjustments on all producer milk, and divided by the total pounds of protein contained in pooled producer milk. Each producer's protein price will then be adjusted for the average somatic cell count of the individual's producer milk. The somatic cell adjustment will be determined by multiplying the cheese price by the appropriate constant for each producer's average somatic cell count.

Each producer will be paid based on total product pounds at the weighted average differential price at the applicable zone, the pounds of protein contained in the producer milk at the protein price adjusted for the producer's average somatic cell count, and the pounds of butterfat contained in the producer milk at the butterfat price.

The value of producer milk to each handler will consist of the sum of the value of pounds of producer milk in Class I times the difference between the Class I and Class III prices, the pounds

of producer milk in Class II times the difference between the Class II price and the Class III price, the value of overage, inventory reclassification, other source milk, receipts from unregulated supply plants, handler location adjustments, the value obtained by multiplying the pounds of skim milk in Class I by the skim milk price, and the value obtained by multiplying the pounds of protein contained in the skim milk in Class II and Class III by the protein price adjusted for the somatic cell content of the handler's receipts. The pounds of protein shall be computed by multiplying the pounds of skim milk in Class II and Class III by the percentage of protein contained in the skim milk of the handler's producer milk.

A handler's obligation to the producer settlement fund will be the difference between the value of producer milk to the handler and the sum of: (a) The value of the handler's receipts of producer milk at the weighted average differential price after adjusting for the producer's location, (b) the value, adjusted for the producer's somatic cell counts, of the protein contained in the handler's receipts of producer milk at the producer protein price, and (c) the value of other source milk at the weighted average differential price adjusted for the location of the plant from which the milk was shipped.

5. Class I Price and Location Adjustments (Order 49)

The Class I price differential and location adjustment provisions of the Indiana order should be amended to bring pricing within the Indiana marketing area into closer alignment with surrounding marketing order areas. The MFI proposal to amend the Indiana Class I price and location adjustment provisions should be adopted in a modified form to minimize intermarket price misalignment and enhance price alignment within the marketing area. A proposal by Hoosier to amend the order's location adjustment provisions should be denied, but changes that would address some of Hoosier's concerns should be made.

Hoosier proposed that the order's location adjustment provisions be changed to provide for adjusting prices downward at locations in the State of Ohio and in parts of Indiana not specifically zoned by the distance of such locations from the Indiana basing points. Proponents argued that the proposed amendment would result in pricing all receipts of producer milk at locations outside the marketing area on an equal basis, and would remove incentives for handlers to associate milk with the Indiana order and then divert

it to Ohio locations at no reduction in the blend price. They also stated that the language "south of the marketing area," in the current location adjustment provision, describing locations at which no location adjustment is applicable, is inexact and confusing. An NFO witness opposed the Hoosier proposal as arbitrary and without economic justification, and stated that it would apply negative location adjustments in areas subject to higher milk prices.

Hoosier's proposal would, indeed, result in the application of negative location adjustments in locations at which higher prices apply, and such a misalignment of prices between orders would be very unlikely to result in more orderly marketing conditions. If the proposal were adopted, the Indiana Class I price adjusted for location at Louisville would be 35 cents less than the price at Louisville under the Louisville-Lexington-Evansville order. Producer prices for milk pooled under the Indiana order but delivered to the Louisville area would fall short of Louisville producer prices by 24 cents more than the current amount by which the Louisville blend price exceeds the Indiana blend price. Similarly, a negative location adjustment under the Indiana order at, for instance, Dayton, Ohio, would result in an Indiana Class I price at Dayton 26 cents lower than the Ohio Valley price for the same location. The difference in producer prices under the two orders at Dayton, Ohio, (or at any Ohio location) would be at least 10-15 cents, with Indiana producer milk receiving the lower price.

A provision such as that proposed by Hoosier would give handlers located outside the Indiana marketing area an incentive to acquire pool status under the Indiana order or to procure supplies of milk pooled under the Indiana order. Price alignment between the Indiana marketing area and locations to its south and east would be most equitable to both handlers and producers who receive and price milk pooled under the adjoining order areas if the Indiana price were adjusted to a level equivalent to that effective at the other order locations where Indiana-pooled milk is received. Accordingly, such language should be included in the order.

A witness for the Milk Foundation of Indiana (MFI), which proposed changes in the order's Class I differential and location adjustments, stated that the Foundation is composed of six proprietary handlers, five of which are pool plant handlers under the Indiana order. The witness testified that the Food and Security Act of 1985 had resulted in the Indiana Class I price differential being increased significantly

more than the Class I price differentials for the surrounding markets were increased. He stated that, based on the location of Indianapolis relative to other population centers in the region, the Indianapolis Class I price is too high and results in an intermarket misalignment of prices. The MFI witness argued that there would be no shortage of milk for Class I use if the Indiana Class I price differential were reduced to correspond more closely with the price levels in surrounding marketing areas. According to the witness, the interorder misalignment of prices has caused Indiana handlers to lose sales to handlers regulated under other orders because they are unable to compete on the basis of price.

The MFI witness also testified in support of the MFI proposal to reduce the rate of location adjustments within the Indiana marketing area. The proposal, as modified at the hearing, would combine the present minus 20- and 30-cent zones into one minus 10-cent zone, and change the location adjustment of the present minus 40-cent zone to minus 30 cents. The witness stated that the location adjustments in the Indiana order do not serve the purpose of attracting milk to the market's principal consumption centers because the price differences are not reflected in differences in payments to cooperative member producers. At the same time, he said, the order's location adjustments create a disparity in price among competing handlers regulated under the Indiana order.

The MFI proposal was opposed by both Hoosier and NFO. Both parties argued that Class I price levels and location adjustments were considered in the national hearing proceeding held in late 1990, and should not be determined for just one market. Hoosier's brief stated that the present Class I differentials were based on the cost of transporting milk to consumption centers from areas of alternate milk supplies available at lower prices, and that the best alternate supply area for Indiana is northeast Iowa, central and western Wisconsin and southeastern Minnesota. Hoosier cited testimony by a representative of Dean Foods Company that Dean experiences no Class I price misalignment between the Indiana and surrounding order areas, and stated that price alignment between Indiana plants and Order 30 (Chicago) bottling plants located 80-100 miles from Chicago needs to be considered. The Hoosier brief concluded that adoption of the MFI proposal would create disorder and disarray in surrounding marketing areas. A comparison of Class I price differentials effective at different

locations within the Indiana and surrounding marketing areas both before and after 1985 shows that Class I differentials were increased significantly more for the Indiana Federal order area than for neighboring marketing areas. The 1985 Class I price increases were 14 cents at Chicago, 21 cents at Louisville, 19 cents in the southern part of the Southern Michigan marketing area, 29 cents in the northern portion of the Southern Illinois market adjoining Indiana, and a maximum of 41 cents under the Ohio Valley order, at Cincinnati. The price increase at Dayton, Ohio, a location closer to the population centers of the Indiana market, was 34 cents. In comparison, the Class I price increase at Indianapolis, the major population area of the Indiana marketing area, was 47 cents.

The price misalignment between markets resulting from the 1985 price increases is particularly noticeable between Chicago and Indianapolis, and between Indianapolis and Louisville, or in a north-south direction. According to the 1985 Household Goods Carriers' Bureau Mileage Guide, of which official notice is taken, the mileage between Chicago and Louisville is 286 miles, with 175 miles from Chicago to Indianapolis, and 111 miles from Indianapolis to Louisville. If the \$.024483 location adjustment rate per 10 miles of distance reflected in the current Chicago-Louisville price difference of 71 cents is applied to the Chicago-Indianapolis distance and the Indianapolis-Louisville distance, the appropriate Class I price differential at Indianapolis would be \$1.83, very close to the \$1.82 level proposed by MFI.

The north-south price alignment in the Indiana order is significant because most of the milk supply for the Indiana market comes from northern Indiana, southern Michigan and the two northern pricing zones of Ohio, and a disproportionate amount of Class I milk is used in the southern part of the Indiana marketing area. Hoosier characterized Wisconsin and Minnesota as the primary alternative sources of supply for the Indiana market. These locations apparently serve as sources of milk for handlers importing supplies of milk that are pooled elsewhere, rather than being sources of producer milk pooled under the Indiana order. Statistics in the record indicate that during only one of the months for which milk production by state and county was published was Wisconsin milk pooled under the Indiana order, with none from Minnesota. The one month in which Wisconsin milk was shown to be pooled under the Indiana order was

May 1988, when only 54 percent of the producer milk pooled under the Indiana order was used in Class I. According to the Hoosier witness' testimony, some of the milk Hoosier arranges to buy in Wisconsin for the Indiana market never moves to Indiana plants.

Another factor that must be considered is price alignment between markets from west to east. In spite of the fact that pricing between Chicago and Louisville would justify a \$1.83 Class I price differential at Indianapolis, an appropriate price alignment between west central Illinois, Indianapolis, and Dayton, Ohio, establishes a minimum Class I price differential at Indianapolis of \$1.90. The current price difference between Champaign, Illinois, and Dayton, Ohio is 29 cents, while the distance between these two points is 223 miles. The resulting rate per hundredweight is \$.0126 per 10 miles of distance. When this rate is applied to the distance between each of these two points and Indianapolis (124 miles to Champaign and 105 miles to Dayton) and the corresponding price level at Indianapolis is computed, an Indianapolis Class I price differential of \$1.90 results. In addition, an Indiana pool distributing plant located at Richmond, Indiana, is located only about 40 miles from an Ohio Valley pool distributing plant at Dayton, Ohio, where the Class I differential is \$2.04. It would be difficult to justify a 20-cent price difference between these two locations (at a rate of \$.0525 per 10 miles), just as it is difficult to defend the current 20-cent price difference between Chicago and Gary, Indiana, located only 28 miles apart (at a rate of \$.067 per ten miles).

Comments and exceptions were filed by several of the handlers doing business in the Indiana marketing area. Hoosier and Milk Marketing, Inc. (MMI), opposed the proposed changes to the Class I differential and location adjustments. The two cooperative groups argued that the recommended decision ignored the standard of supply and demand in changing milk prices by failing to allow for the necessity of moving milk from north to south within the marketing area to assure an adequate supply of milk in the southern part of the marketing area. The exceptors stated that the proposed reduction in the Class I price differential would cause a 6-cent reduction in the uniform price paid to producers, threatening a shortage of milk for fluid use if the recommended price level is adopted. According to the comments, reduction of the Class I price at Indianapolis and narrowing the price difference from the northern part of the marketing area to the southern part will

discourage milk from moving to where it is needed for fluid use.

Both Hoosier and MMI stated that Indiana order Class I prices are not misaligned with those of other orders, and that the proposed changes would result in misalignment and competitive disruptions between locations within the Indiana marketing area. The Hoosier comments pointed out that the restructured location adjustments would add 5 and 10 cents per hundredweight to the cost advantage handlers in zones 4 and 1 currently experience over other handlers distributing milk in those zones. On the basis of this result, the co-ops argued that the recommended changes would impede zone 2, 3 and 4 handlers from moving milk to zone 1, contrary to the purpose of location adjustments.

Both exceptors argued that the national 43-day hearing decision considered proposals to change Class I differentials and price alignment between orders and found no need for doing so.

Dean Foods' comments to the recommended decision began with support for reducing the Class I differential to \$1.90 because it would improve price alignment between Indianapolis and Louisville. The comments concluded that the resulting 6-cent reduction in blend prices to producers is unacceptable, and that the Class I differential should be left at \$2.00, with zone differentials unchanged.

The Dean comments focused primarily on arguments that the zone designation for Fulton County, where Dean has a distributing plant, is incorrect. Dean's comments argued that 20 percent of its Rochester, Indiana, plant's sales compete with those from plants in Lake and Porter Counties in the minus 40-cent zone. At the present time, Dean states, these plants have a 20-cent competitive advantage, which will be changed to 25 cents under the recommended decision. According to Dean, Rochester is 85 miles from the order's lowest price zone, and should have a 16-cent Class I price difference with plants located there, rather than the recommended 25 cents. Dean also argued that the location of other plants with which the Rochester plant competes for sales make it necessary for the Rochester location to be in the same pricing zone (minus 20 cents) as the New Paris plant, rather than in the minus 10-cent zone.

MFI and Kroger supported the recommended Class I price differential and location adjustment changes for Order 49 as re-establishing the historical price relationships that existed between

Order 49 and adjoining markets prior to the 1985 Farm Bill. MFI also stated that the recommended changes will result in more equity among competing handlers in the Indiana marketing area and contribute to more orderly and efficient marketing.

The 10-cent change in the Order 49 Class I price differential and the corresponding 6-cent estimated reduction in prices paid to producers effectuated by this decision should have no discernable impact on the supply and demand for milk in this market. The estimated 6-cent impact on the blend price paid to producers represents approximately one-half of one percent of the average Order 49 blend price for 1988. During 1988, the Minnesota-Wisconsin (M-W) price, upon which all of the prices in the market are based, changed by nearly \$2.00, or over 17 percent of its average. Considering the much greater movements in the basic formula price, which reflects national supply and demand conditions for milk, any attempt to determine the effect of a 6-cent difference in blend prices on supply/demand conditions in the Indiana market would be an exercise in minutiae.

Although Class I price differentials were not changed as a result of the 43-day national hearing for which a final decision was recently issued, failure to make such changes in that proceeding does not preclude changes to Class I price differentials from being made on the basis of hearing records dealing with individual orders. According to the final decision in the national hearing, "The proposals that were considered at the hearing in this proceeding involved possible changes on at least a regional or multi-order basis, possibly even changing all orders. There was no notice given that the appropriate Class I price level for any individual market would be considered outside the context of price alignment among a group of orders."

The reduction in location adjustments between northern and southern Indiana should not impede the movement of milk from the heaviest production area of the market to the primary consumption area, or from locations north of the marketing area to Indiana distributing plants. The changes included in this decision that assure that Indiana pool milk is more likely to be priced at the location to which it is delivered rather than the location from which it is diverted will provide more incentive for milk to move to where it is needed than existed under the previous order provisions. In addition, Indiana blend prices generally exceed blend prices effective under the

Southern Michigan order significantly. When the blend prices of both orders are adjusted for location to the border area between the two States, the Indiana blend price under the amended order will still exceed the Southern Michigan blend price by approximately 10 cents per hundredweight.

The zone price differentials adopted in this decision are intended to correct a Class I differential noticeably higher than in surrounding orders that was mandated by the 1985 Farm Bill. As a secondary effect, the restructured zone differentials should reinstate inter- and intra-market price relationships in effect before the 1985 Farm Bill provisions became effective. Therefore, the adopted differentials should require no more dramatic adjustments in competitive relationships than were experienced at that time.

The zone location of Fulton County should not be changed from the recommended decision. Location pricing is designed to allow milk to move from production areas to consumption centers. Therefore, the appropriate Class I price level at any given distributing plant location should be determined on the basis of its distance from available supplies of milk. Rochester, Indiana, is located at approximately the same distance from the heavy production areas of northern Indiana as are Huntington and Fort Wayne. The location of plants with which the Dean plant at Rochester chooses to compete for sales of fluid milk products has no bearing on the appropriate price for the Rochester location. In addition, the lowest-price zone in the marketing area, from which Dean proposes the Rochester price be determined, is not the area of heaviest milk production and therefore should not be used as the basis for establishing the price at Rochester.

For the foregoing reasons, the Class I price differential at Indianapolis should be reduced to \$1.90. At the same time, location adjustments within the marketing area should be reduced to maintain alignment with adjoining Federal order pricing, especially in the northern portion of the Ohio Valley marketing area. The current \$2.00 price differential should be maintained for a strip of counties on the southern edge of the Indiana marketing area, including Jackson, Jefferson, Jennings, Lawrence, Ripley and Switzerland counties. These counties, located about halfway between Louisville and Indianapolis, can comprise an intermediate pricing zone between the Indiana and Louisville-Lexington-Evansville marketing areas. The current minus 40-cent location adjustment zone in the northwest corner

of the marketing area should become a minus 35-cent pricing zone, to moderate the large price difference between Chicago and Gary, Indiana.

Although the MFI witness was correct in stating that intramarket location adjustments have had little effect in the Indiana market because of the provision allowing milk to be priced at the location from which diverted, this decision adopts amendments to the order that will result in more milk being priced at the location at which it is actually received. Consequently, it is important for reasons of both intermarket and intramarket price alignment to assure that the price differences between various points in the marketing area will accommodate movements of milk from where it is produced to where it is needed for fluid use. The location adjustments in the current minus 20- and minus 30-cent zones therefore should be changed to minus 10- and minus 20-cents, respectively, while the current minus 40-cent adjustment should become a minus 35-cent adjustment. These changes will assure that the current price differences between northeastern Indiana and northwestern Ohio are unchanged.

6. Accountability for .9(c) milk (Order 49)

A proposal by Hoosier to change the accountability to the pool for milk moved directly from producers' farms to pool plants by cooperative associations pursuant to Section .9(c) of the Indiana order from the receiving pool plant operator to the cooperative association handler should be adopted. The proposal, as adopted, would require .9(c) handlers to sell such milk to receiving handlers at classified prices, including component values, and equalize with the pool on the value of the milk so moved. The .9(c) handler would be responsible for the testing of individual producers' milk, and for paying its member producers on the basis of those test results. The Hoosier proposal encountered no opposition, and was supported by NFO. Adoption of the proposal will simplify reporting and accounting for milk and its components under the multiple component pricing plan adopted in this decision.

7. Payments to Producers

a. Due Dates and Late-Payment Charges (Order 49)

A proposal by NFO, joined in by Hoosier, to require timely payment by handlers for producer milk by imposing a one-percent per month late charge on payments not made by the due date

required in the order should be adopted. According to the NFO witness, handler payments made under Orders 33 and 36, which require payments to be made to the market administrator, are made on a much more timely basis than payments for milk under Order 49. The witness stated that the current delay in Order 49 is 6½ days, and attributed the delay to the use of the postal service in making payments rather than using wire transfers. The witness testified that the late payment fee should be assessed by the market administrator, even on monies due to cooperatives from handlers, and paid into the administrative fund. Hoosier supported the proposal on the basis that current technology allows a requirement that payments be required to be received when due, not just mailed by the due date.

The proposal should be adopted to assure that monies due to producers is available to be paid to them when it is due. Handlers currently are able to rely on a delay in the delivery of mailed checks to enhance their own cash-flow positions at the expense of the dairy farmers from whom they obtain milk. The widespread availability of bank transfers of funds makes possible faster payment, which should be passed along to producers as soon as possible. The one-percent late-payment charge will provide an incentive for handlers to make their payments for milk in a timely manner. Payment of any late-payment charges collected into the administrative fund should cover the market administrator's cost of implementing and enforcing timely payment.

b. Seasonal Incentive Payment Plan (All Three Orders)

The Brewster Dairy proposal to provide a seasonal plan to pay dairy farmers, designed to even out monthly milk production under Orders 33, 36 and 49, should be denied. At the present time, producers supplying these three markets receive the uniform price for their monthly milk deliveries. None of the three orders provides any type of seasonal payment program.

Brewster Dairy, Inc., proposed that a unique type of "Louisville" plan be incorporated into each of the three orders. The Order 36 proprietary supply plant operator testified that seasonal pricing programs are needed in these three markets to encourage dairy farmers to level out their milk production during the year so that the amount of milk they produce each month is in better alignment with the amount of milk that fluid processors and manufacturers demand.

Traditionally, more milk is produced in the spring than the fall and fluid bottling plants need more milk for processing in the fall than in the spring. To demonstrate this problem, proponent pointed out that the average daily receipts from producers in November represent only about 85 percent of the amount produced in May while daily Class I use in November is normally about 10 percent greater than in May.

In support of its proposal, Brewster's witness argued that the marketing problems associated with seasonal milk production are complicated by distributing plant operators who contract to buy only enough milk to meet their Class I needs in the spring and rely on others to furnish them with additional supplies in the fall. The Brewster witness stated that these purchasing arrangements, coupled with the seasonality of milk production, result in raising the overall marketing cost to the region's dairy industry. In the spring, he testified, the milk in excess of bottling needs that also exceeds the manufacturing capacity at local plants must be hauled to distant plants for disposal. Conversely, he stated, in the fall supplemental milk from sources beyond the normal procurement area must be transported to distributing plants to furnish the fluid requirements of such plants. According to the witness these extra transportation costs are borne primarily by cooperatives and their member producers. In addition, he said, handlers maintain plant capacity to manufacture reserve milk supplies in the spring and much of that capacity is inefficiently idled in the fall when more of the lower seasonal milk supply is needed for Class I purposes at distributing plants.

Proponent characterized its proposal as a "modest" plan that is designed to reward producers who make the extra effort to increase their milk production in the fall relative to the amount they produced in the prior spring. Brewster proposed that monetary incentives be used to encourage dairy farmers whose milk is pooled under these three orders to gear their milk production toward greater output in the fall. In this regard, the handler proposed that 5 cents per hundredweight be deducted from the pool funds due producers in computing the uniform prices for the months of February through July.

The "Louisville" plan proposed by Brewster is unique in terms of how the money deducted in the prior months of February through July would be returned to dairy farmers. As proposed, the funds would be distributed in the months of September through November, but only to dairy farmers

who qualified for incentive payments. Producers whose average daily milk deliveries in the months of September through November equal 90 percent or more of their daily deliveries in the prior months of February through July would qualify to receive incentive payments. Producers whose average daily deliveries fall below the 90-percent level would not qualify for incentive money.

NFO was supportive of the concept of tailoring milk production to more nearly coincide with the demands of the marketplace. The cooperative's witness insisted, however, that the program must be designed so that the program's costs and benefits are more appropriately aligned. In that regard, he testified that dairy farmers have to spend money to alter their seasonal production patterns, while the benefits of level milk production accrue to handlers because they are able to achieve greater plant operating efficiencies. In recognition of these cost and benefit factors, NFO suggested that Brewster's proposal be modified so that handlers, rather than all of the market's producers, would fund the program. As modified by NFO, handlers would pay a surcharge of 5 cents per hundredweight on their producer milk deliveries assigned to each class during the months of February through July. Such funds would be returned to qualified dairy farmers in the following months of September through November on the same basis proposed by Brewster.

MMI also endorsed the concept of seasonal incentive plans. A spokesman for the cooperative testified that Brewster's proposal has merit, but that MMI would prefer a handler-financed seasonal payment program, as suggested by NFO, to the one proposed by Brewster which would be funded by dairy farmers. He further testified that the dairy industry has made many attempts over the years to encourage dairy farmers to alter their production patterns and thereby increase the efficiency of the entire milk marketing system. The witness asserted that any program designed to address this issue would be welcomed by his association.

A representative of the Hoosier Milk Marketing Agency also supported the concept of seasonal pricing and NFO's modification whereby the incentive money would be derived by increasing the handler Class I prices by 5 cents per hundredweight rather than deducting that rate per hundredweight from the pool funds due producers. In addition, Hoosier testified that this issue should more appropriately be addressed at the national hearing and took the position that a seasonal payment plan should not

be adopted for these three markets unless it is provided under all neighboring Federal orders. The Agency's spokesman stated that adoption of a seasonal payment plan for Orders 33, 36 and 49 and not in surrounding orders would create competitive problems similar to those now experienced by Indiana handlers who are competing with handlers regulated by the Louisville-Lexington-Evansville order, which provides a seasonal base-excess plan to pay dairy farmers.

Hoosier also asked that any seasonal payment program adopted for these markets not be mandatory each year. In that regard, the producer spokesman suggested that the amended orders include provisions that would establish procedures whereby the operation of the seasonal plan could be made inoperative for any year if a review of marketing conditions indicates that it would be unnecessary to encourage additional fall milk production in that particular year.

If Brewster's payment plan had been in effect during 1989, record data show that producers under Orders 33 and 36 would have received about \$2.00 per hundredweight on their eligible milk deliveries during the months of September through November and about 40 percent of the markets' dairy farmers would have qualified for incentive payments. They also indicate that Order 49 producers would have received about \$1.30 per hundredweight for their eligible milk deliveries in such months and about half of the market's dairy farmers would have qualified for incentive payments.

In addition, the record evidence indicates that an Order 36 dairy farmer producing the market's average daily delivery per farm would have had about \$180 deducted from pool funds on his or her behalf through the computation of the uniform prices for February through July of 1989. If such producer marketed the same daily quantity of milk during the following months of September through November as he or she marketed in the spring, the dairy farmer would have received an additional \$370 on 10 percent of his or her deliveries during the ensuing 3-month period. Proponent testified that this may not seem like a lot of money, but if producers know they will be rewarded for extra effort it will motivate them to work hard to qualify for incentive payments.

It is evident from the foregoing that the financial impact of Brewster's proposal on individual dairy farmers would not be substantial. Thus, it is questionable whether the monetary

rewards would be sufficient under the proposed seasonal plans to encourage dairy farmers to make the necessary herd management decisions to gear their production patterns toward greater milk production in the fall. Also, as more producers qualify additional milk for incentive payments, the per hundredweight incentive rate of return for the participating dairy farmers would decrease.

Furthermore, the hearing testimony indicates that there are many differences of opinion among interested parties regarding the adoption of any seasonal payment program for these three markets. These programs affect dairy farmers and, with the exception of the evidence presented by Brewster, no other interested party supported adoption of the proposal as it appeared in the hearing notice.

The hearing participants who represented dairy farmers generally supported the concept of seasonal pricing but stated that Brewster's proposal should be modified in certain respects. For instance, three producer groups (MMI, Hoosier and NFO), which represent a considerable portion of the milk pooled under each of these three orders, endorsed the modification advanced by NFO whereby the incentive money would be generated through higher class prices paid by handlers rather than deducted from money due dairy farmers, as Brewster proposed. Without the support of Hoosier, MMI and NFO, the Brewster proposal lacks widespread support among dairy farmers who supply milk for these three markets.

The funding modification, which shifts the program's cost from producers to handlers, represents a major change in the proposal's impact. It would be inappropriate to adopt such a revision on the basis of this record, since the hearing notice did not alert interested parties that such a proposal would be considered at this hearing and thus provided no opportunity for hearing participants to comment on such a proposition. In view of this consideration and the aforementioned shortcomings, Brewster's proposal must be denied.

Several seasonal incentive plan proposals, including one advanced by MMI, were considered at the national hearing. Such proposals involved many of the same issues that are addressed herein regarding Brewster's three-market proposal. On the basis of the national hearing record, all of the seasonal payment plan proposals were denied.

8. Administrative Expense (Order 36)

The maximum allowable rate of assessment to be paid by handlers to cover the cost of administering the Eastern Ohio-Western Pennsylvania order (Order 36) should be increased to 4 cents per hundredweight. The assessment would continue to be applied to the same milk to which the present assessment applies.

The Act specifies that persons who are regulated shall pay the cost of operating the program through an assessment on the milk handled by regulated persons who are defined as handlers under the order. The present 3-cent per hundredweight maximum allowable rate of assessment has been provided for the administration of Order 36 since the Eastern Ohio-Western Pennsylvania order became effective on July 1, 1968.

A one-cent increase in the maximum allowable rate was proposed by MMI, a cooperative that supplies a considerable portion of the market's total milk needs. A spokesman for the producer group testified that the current maximum funding level of 3 cents per hundredweight is no longer adequate to administer Order 36 effectively.

There was no other testimony on this proposal at the hearing. In briefs, NFO supported the proposed increase and MMI reiterated its hearing position on this issue.

The one-cent increase in the Order 36 maximum rate of administrative assessment was opposed in a brief filed by the Dairy Industry Association of Western Pennsylvania. The handlers' counsel contended that there is no evidence in the record to justify a 33-percent rate increase. He argued that the record fails to adequately demonstrate how much of an increase, if any, is needed and stated that an increase of this magnitude certainly is not warranted.

The Ohio Valley and Eastern Ohio-Western Pennsylvania orders (Orders 33 and 36) are administered under the supervision of a single market administrator who, at the time of the hearing, was headquartered in Columbus, Ohio. Since 1987, consolidated Balance Sheets and Income and Expense Statements for the Administrative Fund, which combine the income and expense activities for the two markets, have been compiled by the market administrator and reported annually to regulated handlers as well as other interested parties. Also, since the market administrator conducts essentially the same verification program in connection with the administration of both orders, the

handler assessment rate has been maintained at the same level in both markets.

Record data for the years 1985-89 show that the administrative expenses associated with the operation of Orders 33 and 36 exceeded the income the market administrator received from assessments by more than \$900,000. They also indicate that an assessment rate of 2.4 cents per hundredweight of milk handled was effective for 1986, 1987 and 1988. It was raised to 2.8 cents for 1989 and further increased to 3 cents per hundredweight for 1990. (Official notice is taken of the market administrator's annual report to all handlers of the Income and Expense Statement for the calendar year ending December 31, 1990.) Since the Order 36 assessment for administration is at the maximum level currently allowed under the order, there is no opportunity for the market administrator to increase the rate to cover any further cost increases. Without the opportunity to increase the assessment rate, additional operating funds can be generated only if substantially greater quantities of milk are pooled under the order or if the expenses of administering the program decline significantly.

Handlers and producers serving the market have jointly asked that a new pricing program be provided to establish handlers' value of Class II and III milk and to pay dairy farmers. A program similar to that requested by the dairy farmers and processors is adopted herein. The implementation and administration of that pricing plan for Order 36 may require the purchase of some new laboratory equipment and the performance of additional administrative duties. Many of the testing expenses associated with the multiple component pricing program will be paid for with money from the marketing service fund. However, since the value of milk used by handlers in Class II and Class III will be established on the basis of the milk's butterfat, protein and somatic cell content, some of the expenses related to establishing the level of these factors in producer milk likely will be paid for with money from the administrative fund. Thus, there is no reason to expect the expenses of administering the order to decline.

The pounds of pooled milk to which the assessment rate applies under orders 33 and 36 has declined considerably during the past few years. For example, receipts of milk from dairy farmers supplying these two markets in 1989 was 14 percent less than the amount pooled in 1985. Also, producer receipts in 1990 were unchanged from 1989.

(Official notice is taken of the publication Federal Milk Order Statistics for December 1990). Current milk price and production trends provide no basis to expect receipts from the market's producers to increase dramatically anytime soon.

It is evident from the foregoing that sufficient funds to cover administrative expenses in the future cannot be guaranteed by either increased milk production or reduced administrative expenses. Accordingly, the proposed one-cent increase in the maximum allowable assessment rate is adopted as the best way of assuring continued adequate funding for the effective administration of the Eastern Ohio-Western Pennsylvania order.

This one-cent increase for Order 36 will establish the same 4-cents per hundredweight maximum allowable administrative assessment rate that exists under Orders 33 and 49, as well as most other Federal milk orders. Increasing the Order 36 maximum permissible administrative assessment rate to 4 cents per hundredweight will give the market administrator the necessary flexibility to generate the financial resources needed to properly administer the order, as amended. It also should enable him to establish and maintain an appropriate financial reserve that is within the Department's guidelines.

Providing a higher maximum rate of assessment in the order does not mean that the higher rate will apply automatically when the amended order becomes effective. The amendment gives the market administrator the discretionary authority to set the rate at any level up to the maximum specified in the order. Because of that discretion, when the amended order becomes effective the market administrator may decide that no change in the effective assessment rate is necessary, or he may find that some increase is warranted, but not up to the maximum allowed.

Pennsylvania Farmers Union filed comments objecting to the proposed increase in the ceiling on administrative assessments in Federal Order 36 to the levels of Orders 33 and 49. Pennsylvania Farmers Union stated that raising fees to the levels in other orders simply because they are the levels used in those areas is not sufficient justification. However, the organization stated, an increased burden in administering a component pricing system is a reasonable cause for such an increase.

As described in the preceding paragraphs, an increase in the Order 36 maximum allowable administrative assessment is necessary to provide for

the optimum administration of the order, and not merely to raise the level of the assessment to that prevailing in Orders 33 and 49. In addition, it would be inequitable to fund the administrative costs of Order 36 at the expense of Order 33 handlers.

9. Marketing Service Assessments (All Three Orders).

The maximum rate of deduction from payments to nonmember producers for the cost of providing marketing services such as butterfat, protein and somatic cell testing and market information for nonmember producers should be increased to 7 cents per hundredweight under the three orders (Orders 33, 36 and 49) involved in this proceeding. The increase is needed to assure sufficient funding to cover the expenses incurred by the market administrators in providing such services to producers for whom the services are not provided by a cooperative association.

Currently, 6 cents per hundredweight is the maximum allowable deduction for such services under Order 33, and 5 cents is the maximum under Orders 36 and 49. These maximum rates have been effective under the individual orders for many years. For example, the 6-cent maximum has been provided in the Ohio Valley order since August 1, 1970. The 5-cent rate has been provided in the Eastern Ohio-Western Pennsylvania order since July 1, 1968, and in the Indiana order since January 1, 1969.

Milk Marketing, Inc. and the Hoosier Milk Marketing Agency proposed that the limits on the rates of deduction be raised to 7 cents per hundredweight under the three orders. These producer organizations represent a substantial portion of the milk supply pooled under each of the 3 orders. The producer spokesman testified that the cost of performing marketing services for dairy farmers has increased considerably over the years. He also testified that the market administrators have streamlined their operations to the extent possible and adopted the latest office and laboratory technology available in an attempt to provide the maximum services to dairy farmers for the lowest possible cost. He contended that the extent to which costs can be reduced before affecting the program's effectiveness is limited.

In support of their proposal, proponents argued that the maximum rates of deduction for marketing services provided under the three orders represent much smaller percentages of the markets' blend prices now than when the rates originally were provided. Proponent witness stated that over the years the market administrators have

expanded their marketing services for dairy farmers and that the cost of performing these functions has increased. The witness testified that the marketing service assessment proposal is designed to complement the cooperatives' proposal to provide multiple component pricing plans for these three markets. Since the new pricing plan will require accurate measurement of the butterfat, protein and somatic cell content of producer milk, additional milk testing duties will be imposed on the market administrators.

No other interested party testified on this issue at the hearing. In briefs, NFO agreed that an increase in the maximum rates of deduction for marketing services would be needed with the implementation of component pricing plans under these three orders.

Opposition to the proposed increase in the maximum allowable marketing service assessment was expressed in a brief filed on behalf of the Dairy Industry Association of Western Pennsylvania. The brief argued that the record fails to justify rate increases of up to 40 percent for marketing services. Counsel for the handlers stated that proponents offered only vague and nonspecific reasons to support their proposal and relied primarily on the fact that the maximum rates had not been changed for several years and that inflationary pressures have resulted in increased operating costs. The brief argued that these generalities do not provide an adequate basis for increasing the rates and insisted that if higher maximum rates are justified, they certainly would not have to be raised to the 7-cent level proposed by MMI and Hoosier.

The marketing service programs for these three orders are provided under the supervision of two market administrators. The program for the Ohio Valley and Eastern Ohio-Western Pennsylvania orders (Orders 33 and 36) was, at the time of the hearing, conducted under the auspices of the market administrator who was headquartered in Columbus, Ohio. The orders are still administered by a single market administrator. Since 1987, Balance Sheets and Income and Expense Statements for the Marketing Service Fund for these two markets have been published annually on a combined basis for nonmember producers and other interested parties. Since the market administrator provides essentially the same marketing service program for producers under both orders, the rate of deduction to cover such services under Orders 33 and 36 has been maintained

at the 5-cent maximum level provided in Order 36.

Similarly, the marketing service program for the Chicago Regional and Indiana orders (Orders 30 and 49) is operated under the jurisdiction of the market administrator who is located in Glen Ellyn, Illinois. Since 1987, Balance Sheets and Income and Expense Statements for the Marketing Service Fund showing combined activities for these two markets have been reported annually to nonmember producers and other interested parties. Similar services are provided by the market administrator for nonmember dairy farmers supplying both markets and 5 cents per hundredweight, which is the maximum provided under both orders, has been deducted from payments to dairy farmers to cover the expenses associated with providing these services.

Record data for Orders 33 and 36 show that for the years of 1985-1989 the marketing service program expenses exceeded the amount deducted from producer payments for such services by a net amount of almost \$127,000. They also indicate that expenses exceeded deductions in 4 of the 5 years and that most of the income shortfall, \$82,000, was accounted for in 1989. Marketing service expenses in these two markets for the 5-year period averaged 5.1 cents per hundredweight of nonmember milk pooled. For 1985-89, expenses represented 5.0, 4.9, 5.1, 5.1 and 5.4 cents per hundredweight respectively of such producer milk.

Record data for Orders 30 and 49 show that the expenses incurred by the market administrator in providing marketing services for nonmember dairy farmers in these two markets for the 3-year period of 1987-89 exceeded the amount deducted from producer payments to cover such expenses by almost \$10,000. The 3-year net figure, however, does not demonstrate the seriousness of the income shortfall because in 1989 expenses exceeded the amount deducted by more than \$38,000. The data also show that the marketing service program expenses in these two markets for the 3-year period averaged 5.1 cents per hundredweight of nonmember milk pooled. For the years of 1987-89, expenses represented 4.6, 4.8 and 5.7 cents per hundredweight, respectively, of such producer milk.

It is evident from the foregoing that the 5-cent deductions from producer payments for marketing services in these 3 markets have been inadequate to cover the expenses incurred in the performance of such duties by the market administrators. It also shows that the financial situations are becoming

progressively worse each year. In addition, the multiple component pricing plan adopted in this decision is going to require additional testing activities. Since not all handlers are equipped to make all of the determinations that will be required under the amended order, many of these extra duties will have to be performed by the market administrators responsible for the administration of these three orders.

The 7-cent maximum rate of deduction for marketing services proposed by MMI and Hoosier should be provided in the three orders involved in this proceeding. These higher rates should give the market administrators the necessary flexibility to conduct effective marketing service programs, including any additional duties relating to the implementation and administration of the new pricing program that will be incorporated in the three orders.

Provision of a 7-cent maximum rate does not mean that the 7-cent rate will become effective automatically. Maximum rather than fixed rates of deduction are specified in the orders because the relationship between income and expenses for these funds is subject to many variables. Changes in the pounds of nonmember milk marketed and the rate assessed on these marketings increase or decrease the income of the marketing services funds while changes in order requirements and the expenses of providing marketing services result in changes in total outlays. Because of such variations, an increase in maximum allowable assessments will give the market administrators the discretionary authority to set the rates of deduction for marketing services at levels necessary to cover the expense of providing marketing services. If the market administrators decide that rates below the upper limits adopted in the amended orders will provide sufficient funding to conduct an adequate program for nonmember producers they may use their discretionary authority to do so.

10. Conforming changes

The provisions specifying reporting requirements and the computation of handlers' obligations to the pool and to producers have been changed as needed to assure that the multiple component pricing plan adopted herein will be practicable. In addition, the current requirement under both the Ohio Valley and Eastern Ohio-Western Pennsylvania milk orders that handlers report each producer's days of production is removed in the accompanying order language changes.

Neither of these orders contains a base plan or any other provisions that would necessitate such a reporting requirement.

The proposed amendments to order language included with this decision are based on the amended order language published for these three orders with the final decision for the 1990 national hearing for all orders, issued in early 1993.

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 Ohio Valley, Eastern Ohio-Western Pennsylvania, and Indiana 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 aforesaid marketing areas, 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.

(d) It is hereby found that the necessary expense of the market administrator for the maintenance and functioning of such agency for Order 36 will require the payment by each handler, as his pro rata share of such expense, 4 cents per hundredweight or such lesser amount as the Secretary may prescribe, with respect to milk specified in § 1036.85 of the aforesaid tentative marketing agreement and the order as proposed to be amended.

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 Ohio Valley, Eastern Ohio-Western Pennsylvania, and Indiana 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.

Referendum Order to Determine Producer Approval; Determination of Representative Period; and Designation of Referendum Agent

It is hereby directed that a referendum be conducted and completed on or before the 30th day from the date this decision is issued, in accordance with the procedure for the conduct of referenda (7 CFR 900.300-311), to determine whether the issuance of the attached order as amended and as hereby proposed to be amended, regulating the handling of milk in the Eastern Ohio-Western Pennsylvania marketing area is approved or favored by producers, as defined under the terms of the order, 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 area. The representative period for the conduct of such referendum is hereby

determined to be October 1992. The agent of the Secretary to conduct such referendum is hereby designated to be Marvin A. Baumer.

Determination of Producer Approval and Representative Period

October 1992 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 Ohio Valley and Indiana 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 1033, 1036 and 1049

Milk marketing orders.

Dated: June 9, 1993

Eugene Branstod,

Assistant Secretary, Marketing and Inspection Services.

Order Amending the Orders Regulating the Handling of Milk in the Ohio Valley, Eastern Ohio-Western Pennsylvania, and Indiana 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 agreements and to the orders regulating the handling of milk in the aforesaid 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; and 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 are applicable only to persons in the respective classes of industrial or commercial activity specified in, marketing agreements upon which a hearing has been held; and

(4) It is hereby found that the necessary expense of the market administrator for the maintenance and functioning of such agency for the Eastern Ohio-Western Pennsylvania areas will require the payment by each handler, as his pro rata share of such expense, 4 cents per hundredweight or such lesser amount as the Secretary may prescribe, with respect to milk specified in § 1036.85.

Order Relative to Handling

It is therefore ordered that on and after the effective date hereof, the handling of milk in the specified marketing areas shall be in conformity to and in compliance with the terms and conditions of the orders, 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 July 30, 1992, and published in the *Federal Register* on August 13, 1992 (57 FR 36536), 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 paragraphs (a)(1)(i), (a)(4), (b)(1), (b)(1)(ii) and (b)(3) of §§ 1033.30 and 1036.30. Corresponding changes in § 1049.30 are in paragraphs (a), (a)(6)(ii), and (c)(1). Modifications are also necessary in §§ 1033.32(e)(4), and 1036.32 (d) and (f).

b. Additional changes due to the treatment of the somatic cell adjustment have been made in §§ 1033.60(i), 1036.60(i) and 1049.60(i); §§ 1033.62, 1036.62 and 1049.62; §§ 1033.66,

1036.66 and 1049.66; and §§ 1033.71(b) and 1036.71(b).

c. Language has been added to §§ 1033.50(d), 1036.50(d) and 1049.50(d) to specify rounding in the computation of the butterfat price.

d. Language in §§ 1033.61(a) and 1033.62(a) is changed to allow for the manner in which milk described in § 1033.43(d) is pooled.

e. Changes in the qualification standards for pool distributing plants require changes in § 1049.7, paragraphs (a)(1), (a)(1)(ii) and (a)(1)(iii).

f. Changes in § 1049.13, paragraphs (e)(5) and (f), are made to clarify the application of the location adjustment provisions.

g. Corrections have been made in §§ 1049.32(a) and 1049.52, paragraphs (a)(6), (a)(7) and (b).

PART 1033—MILK IN THE OHIO VALLEY MARKETING AREA

1. The authority citation for 7 CFR parts 1033, 1036 and 1049 continues to read as follows:

Authority: Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.

2. Section 1033.7 is amended by revising the introductory language of paragraph (b), redesignating paragraphs (b)(2) and (b)(3) as paragraphs (b)(3) and (b)(4), adding a new paragraph (b)(2); and changing the words "50 percent" in the introductory text of paragraph (c) and in paragraph (c)(2) to "35 percent"; to read as follows:

§ 1033.7 Pool plant.

* * * * *

(b) A supply plant from which 35 percent or more during the months of January through November, and 30 percent in December, of the receipts at such plant from producers (including producer milk diverted from the plant but excluding milk diverted to such plant) and from handlers described in § 1033.9(c) is delivered by transfer or diversion as fluid milk products except filled milk, to pool distributing plants qualified pursuant to paragraph (a) of this section, subject to the following conditions:

(1) * * *

(2) Shipments to be used in determining qualifying percentages shall be milk transferred or diverted and physically received by distributing pool plants, less any transfers or diversions of bulk fluid milk products from such distributing pool plants;

* * * * *

2. In § 1033.13, paragraphs (e)(2), (e)(3) and (f) are revised to read as follows:

§ 1033.13 Producer milk.

(e) * * *

(2) The operator of a pool plant may divert the milk of any producer that is not under the control of a cooperative association that diverts milk during the month pursuant to paragraph (e)(3) of this section. The operator of such plant may divert a total quantity of milk not exceeding 50 percent during the months of September through November, January and February, and 60 percent during the month of December, of the producer milk physically received at or diverted from such pool plant during the month;

(3) A cooperative association may divert an aggregate quantity of milk not exceeding 50 percent during the months of September through November, January and February, and 60 percent during the month of December, of the producer milk that the cooperative association caused to be physically received at or diverted from pool plants during the month; and

(f) Milk diverted pursuant to paragraph (d) or (e) of this section shall be priced at the location of the plant where it is received, except that for the months of March through August the uniform price applicable to milk of producers located within the State of Ohio or the Michigan counties of Hillsdale, Lenawee, Monroe, Jackson and Washtenaw that is diverted to a plant located outside the marketing area and outside the State of Ohio shall not be adjusted downward below the uniform price for the month applicable at the location of the producer's farm. *Provided*, that 65 percent or more of such producer's milk is delivered to a plant or plants at which the same or a higher uniform price is applicable during the preceding months of September through February.

3. Section 1033.30 is amended by revising paragraphs (a)(1)(i), (a)(3)(ii), (a)(4) and (b) to read as follows:

§ 1033.30 Reports of receipts and utilization.

(a) * * *

(1) * * *

(i) Producer milk, showing in the case of milk received directly from each producer the pounds of milk, the butterfat and milk protein contained in the milk, and the somatic cell count of the milk;

(3) * * *

(ii) Transfers and diversions to other plants, and the butterfat and milk protein content of such milk;

(4) Such other information with respect to the receipts and utilization of skim milk, butterfat and milk protein, and somatic cell count, as the market administrator may prescribe;

(b) Each cooperative association shall report:

(1) The quantities of skim milk, butterfat and milk protein, and somatic cell count contained in milk from producers for which it is the handler pursuant to § 1033.9 (b) or (c), showing:

(i) The quantity of milk delivered to each plant; and

(ii) For each producer the pounds of milk, butterfat and milk protein tests, and the somatic cell count;

(2) The utilization of all skim milk and butterfat required to be reported pursuant to paragraph (b)(1) of this section, except that contained in producer milk described in § 1033.13(b); and

(3) Such other information with respect to its receipts and utilization of skim milk, butterfat and protein, and somatic cell count as the market administrator may prescribe; and

4. Section 1033.31 is amended by revising paragraph (a)(2), the second sentence of paragraph (b), and paragraph (c), to read as follows:

§ 1033.31 Payroll reports.

(a) * * *

(2) The total pounds of milk and, with respect to final payments, the average butterfat and protein content and somatic cell count of the milk for which payment is being made;

(b) * * * Such payroll shall report for each dairy farmer who would have been a producer if the plant had been fully regulated in the same manner as prescribed for reports required by paragraph (a) of this section.

(c) On or before the 22nd day after the end of the month, each cooperative association with respect to the milk of producers shall submit to the market administrator the association's completed producer payroll which shall list the pounds of milk received, the average butterfat and milk protein content thereof, the somatic cell count of the milk, and the rate and net amount of the payment made to such dairy farmer, together with the amount and nature of any deductions involved.

5. Section 1033.32 is amended by revising paragraphs (e)(2), (e)(4) and (e)(5), and paragraph (f) to read as follows:

§ 1033.32 Other reports.

(e) * * *

(2) The total pounds of producer milk received from such producer, its average

butterfat and milk protein content, and its somatic cell content;

(4) The total pounds of skim milk, butterfat and milk protein, and the somatic cell count of milk received from a handler described in § 1033.9(c); and

(5) The total pounds of skim milk, butterfat and protein in bulk fluid milk products received from a pool plant operated by a cooperative association.

(f) On or before the second day prior to the reporting dates specified in paragraphs (c) and (e) of this section, each cooperative association that operates a pool plant from which bulk fluid milk products were transferred or diverted to another pool plant within the time periods described in paragraphs (c) and (e) of this section shall report to each such pool plant operator and the market administrator the name and location of each transferor-plant and the total pounds, butterfat and milk protein included in the bulk fluid milk products transferred or diverted from each such plant.

6. Section 1033.41 is amended by revising the second sentence of paragraph (c) to read as follows:

§ 1033.41 Shrinkage.

(c) * * * If the operator of the plant to which the milk is delivered purchases such milk on the basis of weights determined from its measurement at the farm, with protein and butterfat tests and somatic cell counts determined from farm bulk tank samples, the applicable percentage for the cooperative association shall be zero.

7. Section 1033.43 is amended by revising paragraph (d) to read as follows:

§ 1033.43 General classification rules.

(d) Bulk fluid milk products transferred or diverted from a pool plant operated by a cooperative association to another pool plant shall be classified in accordance with the rules set forth in § 1033.42(a) and the value thereof shall be used to compute the receiving handler's pool obligation for such milk pursuant to § 1033.60 (a), (b), (h), (i) and (j).

8. Section 1033.50 is amended by revising the section heading, revising the introductory language, and adding new paragraphs (d), (e) and (f), to read as follows:

§ 1033.50 Class and component prices.

Subject to the provisions of § 1033.52, the class and component prices for the month, per hundredweight or per pound, shall be as follows:

(d) *Butterfat price.* The butterfat price per pound shall be the total of the following steps, rounded to the nearest whole cent:

(1) The skim milk price per hundredweight for the month, computed pursuant to paragraph (f) of this section, divided by 100; and

(2) The butterfat differential for the month, computed pursuant to § 1033.73 multiplied by 10.

(e) *Milk protein price.* The price per pound for milk protein shall be computed by subtracting from the Class III price the butterfat price multiplied by 3.5, and dividing the result by the average protein content of the milk on which the basic formula price is based for the previous month as reported by the Department and adjusted for the current month by the Dairy Division, and rounding the result to the nearest whole cent.

(f) *Skim milk price.* The skim milk price per hundredweight shall be computed by subtracting from the Class III price the butterfat differential computed pursuant to § 1033.73 times 35, and rounding the result to the nearest whole cent.

9. Section 1033.53 is revised to read as follows:

§ 1033.53 Announcement of class and component prices.

The market administrator shall announce on or before:

(a) The fifth day of each month:

(1) The Class I price for the following month;

(2) The Class III price for the preceding month;

(3) The butterfat differential for the preceding month;

(4) The butterfat price, the milk protein price, and the skim milk price computed pursuant to § 1033.50 (d), (e) and (f) for the preceding month; and

(5) The monthly average price for 40-pound blocks of cheese at the National Cheese Exchange (Green Bay, Wisconsin) for the preceding month.

(b) The 15th day of each month, the Class II price for the following month computed pursuant to § 1033.50(b).

10. The undesignated center heading before § 1033.60 is revised to read "DIFFERENTIAL POOL AND HANDLER OBLIGATIONS"

11. Section 1033.60 is revised to read as follows:

§ 1033.60 Computation of handlers' obligations to pool.

The market administrator shall compute each month for each handler defined in § 1033.9(a) with respect to each of such handler's pool plants, and for each handler defined in § 1033.9 (b) and (c), an obligation to the pool computed by adding the following values:

(a) The pounds of producer milk in Class I as determined pursuant to § 1033.44, and the pounds of bulk fluid milk products received from a pool plant operated by a cooperative association pursuant to § 1033.43(d) in Class I, both multiplied by the difference between the Class I price (adjusted pursuant to § 1033.52) and the Class III price;

(b) The pounds of producer milk in Class II as determined pursuant to § 1033.44, and the pounds of bulk fluid milk products received from a pool plant operated by a cooperative association pursuant to § 1033.43(d) in Class II, both multiplied by the difference between the Class II price and the Class III price;

(c) The value of the product pounds, skim milk, and butterfat in overage assigned to each class pursuant to § 1033.44(a)(14) and the value of the corresponding protein pounds associated with the skim milk subtracted from Class II and Class III pursuant to § 1033.44(a)(14), by multiplying the skim milk pounds so assigned by the percentage of protein in the handler's receipts of producer skim milk during the month, as follows:

(1) The hundredweight of skim milk and butterfat subtracted from Class I pursuant to § 1033.44(a)(14) and the corresponding step of § 1033.44(b), multiplied by the difference between the Class I price adjusted for location and the Class III price, plus the hundredweight of skim milk subtracted from Class I pursuant to § 1033.44(a)(14) multiplied by the skim milk price, plus the butterfat pounds of overage subtracted from Class I pursuant to § 1033.44(b) multiplied by the butterfat price;

(2) The hundredweight of skim milk and butterfat subtracted from Class II pursuant to § 1033.44(a)(14) and the corresponding step of § 1033.44(b) multiplied by the difference between the Class II price and the Class III price, plus the protein pounds in skim milk subtracted from Class II pursuant to § 1033.44(a)(14) multiplied by the protein price, plus the butterfat pounds of overage subtracted from Class II pursuant to § 1033.44(b) multiplied by the butterfat price;

(3) The protein pounds in skim milk overage subtracted from Class III pursuant to § 1033.44(a)(14) multiplied by the protein price, plus the butterfat pounds of overage subtracted from Class III pursuant to § 1033.44(b) multiplied by the butterfat price;

(d) The value of the product pounds, skim milk, and butterfat subtracted from Class I or Class II pursuant to § 1033.44(a)(9) and the corresponding step of § 1033.44(b), and the value of the protein pounds associated with the skim milk subtracted from Class II pursuant to § 1033.44(a)(9), computed by multiplying the skim milk pounds so subtracted by the percentage of protein in the handler's receipts of producer skim milk during the previous month, as follows:

(1) The value of the product pounds, skim milk and butterfat subtracted from Class I pursuant to § 1033.44(a)(9) and the corresponding step of § 1033.44(b) applicable at the location of the pool plant at the current month's Class I-Class III price difference and the current month's skim milk and butterfat prices, less the Class III value of the milk at the previous month's protein and butterfat prices;

(2) The value of the hundredweight of skim milk and butterfat subtracted from Class II pursuant to § 1033.44(a)(9) and the corresponding step of § 1033.44(b) at the current month's Class II-Class III price difference and the current month's protein and butterfat prices, less the Class III value of the milk at the previous month's protein and butterfat prices;

(e) The value of the product pounds, skim milk and butterfat subtracted from Class I pursuant to § 1033.44(a)(7) (i) through (iv), and the corresponding step of § 1033.44(b), excluding receipts of bulk fluid cream products from another order plant, applicable at the location of the pool plant at the current month's Class I-Class III price difference;

(f) The value of the product pounds, skim milk and butterfat subtracted from Class I pursuant to § 1033.44(a)(7) (v) and (vi) and the corresponding step of § 1033.44(b) applicable at the location of the transferor-plant at the current month's Class I-Class III price difference;

(g) The value of the product pounds, skim milk and butterfat subtracted from Class I pursuant to § 1033.44(a)(11) and the corresponding step of § 1033.44(b), excluding such hundredweight in receipts of bulk fluid milk products from an unregulated supply plant to the extent that an equivalent quantity disposed of to such plant by handlers fully regulated by any Federal order is classified and priced as Class I milk and

is not used as an offset for any other payment obligation under any order, applicable at the location of the nearest unregulated supply plants from which an equivalent volume was received at the current month's Class I-Class III price difference.

(h) The pounds of skim milk in Class I producer milk, as determined pursuant to § 1033.44, and the pounds of skim milk in Class I bulk fluid milk products received from a pool plant operated by a cooperative association pursuant to § 1033.43(d), both multiplied by the skim milk price for the month computed pursuant to § 1033.50(f).

(i) The pounds of protein in skim milk in Class II and Class III, computed by multiplying the skim milk pounds so assigned by the percentage of protein in the handler's receipts of producer skim milk during the month for each report filed, separately, and the pounds of protein in Class II and Class III skim milk in bulk fluid milk products received from a pool plant operated by a cooperative association pursuant to § 1033.43(d), both multiplied by the protein price for the month, computed pursuant to § 1033.50(e) and adjusted pursuant to § 1033.66 for the weighted average somatic cell content of the handler's receipts of milk.

(j) The pounds of butterfat in all three classes as determined pursuant to § 1033.44, and the pounds of butterfat in bulk fluid milk products received from a pool plant operated by a cooperative association pursuant to § 1033.43(d), both multiplied by the butterfat price for the month computed pursuant to § 1033.50(d).

(k) Subtract, for reconstituted milk made from receipts of nonfluid milk products, an amount computed by multiplying \$1.00 (but not more than the difference between the Class I price applicable at the location of the pool plant and the Class III price) by the hundredweight of skim milk and butterfat contained in receipts of nonfluid milk products that are allocated to Class I use, provided that the handler establishes a disposition of labeled reconstituted fluid milk products; and

(l) Exclude, for pricing purposes under this section, receipts of nonfluid milk products that are distributed as labeled reconstituted milk for which payments are made to the producer-settlement fund of another order under § 1033.76(c).

12. Section 1033.61 is revised to read as follows:

§ 1033.61 Computation of weighted average differential value.

For each month the market administrator shall compute the weighted average differential value for milk received from all producers as follows:

(a) Combine into one total the values computed pursuant to § 1033.60, paragraphs (a) through (g) and (k) and (l), excluding the values in paragraphs (a) and (b) associated with bulk fluid milk products received from a pool plant operated by a cooperative association pursuant to § 1033.43(d), for all handlers who made reports pursuant to § 1033.30 and who made payments pursuant to § 1033.71 for the preceding month;

(b) Add an amount equal to the total value of the minus location adjustments computed pursuant to § 1033.74(a);

(c) Subtract an amount equal to the total value of the plus location differentials computed pursuant to § 1033.74(a);

(d) Add an amount equal to not less than one-half the unobligated balance in the producer-settlement fund;

(e) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(1) The total hundredweight of producer milk; and

(2) The total hundredweight for which a value is computed pursuant to § 1033.60(g).

(f) Subtract not less than 4 cents nor more than 5 cents per hundredweight. The result shall be the "Weighted Average Differential Price";

13. New §§ 1033.62 through 1033.66 are added under the undesignated center heading "Differential Pool and Handler Obligations", as follows:

§ 1033.62 Computation of producer protein price.

For each month the market administrator shall compute the producer protein price to be paid to all producers for the pounds of protein in their milk, as follows:

(a) Combine into one total the values computed pursuant to § 1033.60, paragraphs (h) and (i), excluding the values associated with bulk fluid milk products received from a pool plant operated by a cooperative association pursuant to § 1033.43(d), for all handlers who made reports pursuant to § 1033.30 and who made payments pursuant to § 1033.71 for the preceding month;

(b) Add all of the negative adjustments and subtract all of the positive adjustments determined for

each producer's somatic cell count pursuant to § 1033.66;

(c) Divide the resulting amount by the total pounds of protein in producer milk; and

(d) Round to the nearest whole cent. The result is the "Producer protein price."

§ 1033.63 Uniform price.

A uniform price for producer milk containing 3.5 percent butterfat shall be computed by adding the weighted average differential price determined pursuant to § 1033.61 to the basic formula price for the month.

§ 1033.64 Announcement of weighted average differential price, producer protein price, and uniform price.

The market administrator shall announce publicly on or before the 12th day after the end of the month the weighted average differential price computed pursuant to § 1033.61, the producer protein price computed pursuant to § 1033.62, and the uniform price computed pursuant to § 1033.63(a).

§ 1033.65 Value of producer milk.

The value of producer milk shall be the sum of:

(a) The weighted average differential price computed pursuant to § 1033.61 and adjusted pursuant to § 1033.74, multiplied by the total hundredweight of producer milk received from the producer;

(b) The producer protein price computed pursuant to § 1033.62 and adjusted pursuant to § 1033.66, multiplied by the total milk protein contained in the producer milk received from the producer; and

(c) The butterfat price computed pursuant to § 1033.50(d) multiplied by the total butterfat contained in the producer milk received from the producer.

§ 1033.66 Computation of somatic cell adjustment.

(a) For each producer, an adjustment to the producer protein price for the somatic cell count of the producer's milk shall be determined by multiplying the constant associated with the appropriate somatic cell count interval in the table in paragraph (b) of this section by the average price for the month of 40-pound blocks of cheese at the National Cheese Exchange at Green Bay, WI, as reported monthly by the Dairy Division, Agricultural Marketing Service. If a handler has not determined a monthly average somatic cell count, it

will be determined by the market administrator.

(b) The following table shows the factors and constants to be used in computing the somatic cell adjustment.

FACTORS AND CONSTANTS TO BE USED IN COMPUTING THE SOMATIC CELL ADJUSTMENT

Somatic cell counts	Factors	Constants for computing the somatic cell adjustment
1 to 50,000	.300	.09375
51,000 to 100,000	.200	.062500
101,000 to 150,000	.150	.046875
151,000 to 200,000	.100	.031250
201,000 to 250,000	.050	.015625
251,000 to 300,000	.025	.0078125
301,000 to 350,000	.000	.000000
351,000 to 400,000	.000	.000000
401,000 to 450,000	-.025	-.0078125
451,000 to 500,000	-.050	-.015625
501,000 to 550,000	-.075	-.0234375
551,000 to 600,000	-.100	-.031250
601,000 to 650,000	-.125	-.0390625
651,000 to 700,000	-.150	-.046875
701,000 to 750,000	-.200	-.062500
751,000 and above	-.250	-.078125

14. In § 1033.70, paragraph (b) is revised to read as follows:

§ 1033.70 Producer-settlement fund.

* * * * *

(b) The difference between the amount added pursuant to § 1033.61(d) and the amount resulting from the subtraction pursuant to § 1033.61(f) shall be deposited in, or withdrawn from, this fund, as the case may be.

15. Section 1033.71 is amended by revising the introductory language of paragraph (b) and paragraph (b)(1) to read as follows:

§ 1033.71 Payments to the market administrator.

* * * * *

(b) Subject to paragraph (c) of this section, each handler shall pay to the market administrator on or before the 15th day after the end of each month the value of such handler's milk pursuant to § 1033.60 (a) through (l) and the value of bulk fluid milk products received from a pool plant operated by a cooperative association pursuant to § 1033.43(d) as determined pursuant to § 1033.60 (a), (b), (h), (i) and (j), less:

(1) The amount obtained from multiplying the weighted average differential price applicable at the location of the plants from which the other source milk is received (not to be less than zero) by the hundredweight of other source milk for which a value is computed pursuant to § 1033.60(g);

* * * * *

16. Section 1033.72 is amended by revising paragraphs (b) introductory text and (d)(2) to read as follows:

§ 1033.72 Payments to producers and to cooperative associations.

* * * * *

(b) On or before the 17th day after the end of the month, the market administrator shall make payment, subject to paragraphs (c) and (d) of this section, to each producer for milk received from such individual producer and to each cooperative association for bulk fluid milk products delivered from its pool plant to another pool plant during the month by handlers from whom the appropriate payments have been received pursuant to § 1033.71(b) of the amount determined pursuant to § 1033.65, less:

* * * * *

(d) * * *

(2) The total pounds and, with respect to final payments, the average butterfat and protein content and somatic cell count of the milk for which payment is being made;

* * * * *

17. Section 1033.86 is amended by revising paragraph (a) to read as follows:

§ 1033.86 Deduction for marketing services.

(a) The market administrator, in making payments to each producer pursuant to § 1033.72, shall deduct 7 cents per hundredweight, or such lesser amount as the Secretary may prescribe,

with respect to the milk (except a handler's own farm production) of such producer for whom the marketing services set forth in paragraph (b) of this section are not being performed by a cooperative association as determined by the Secretary.

* * * * *

PART 1036—MILK IN THE EASTERN OHIO-WESTERN PENNSYLVANIA MARKETING AREA

1. Section 1036.7 is amended by revising paragraph (b) to read as follows:

§ 1036.7 Pool plant.

* * * * *

(b) A supply plant from which not less than 40 percent during the months of September, October and November, not less than 35 percent during the months of January and February, and not less than 30 percent in all other months, of the total quantity of milk approved by a duly constituted health authority for fluid consumption that is physically received at such plant from dairy farmers (including milk diverted from the plant as producer milk pursuant to § 1036.13 but excluding milk received as diverted milk) and handlers defined in § 1036.9(c) is transferred or diverted to and physically received in the form of fluid milk products, except filled milk, at pool plants qualified under paragraph (a) of this section or disposed of as route disposition in the marketing area, subject to the following conditions:

(1) At least one tank load of Grade A fluid milk products (not less than 45,000 pounds) must be shipped from the supply plant to a pool distributing plant during one of the months of September, October and November; and

(2) Shipments to be used in determining qualifying percentages shall be milk transferred or diverted and physically received by distributing pool plants, less any transfers or diversions of bulk fluid milk products from such distributing pool plants.

2. Section 1036.13 is amended by revising the reference "(e), (f) and (g)" in paragraphs (a)(3) and (b) to "(e) and (f)", revising paragraphs (e), (f) and (h) to read as follows, and removing and reserving paragraph (g):

§ 1036.13 Producer milk.

(e) During March through August, subject to the conditions of paragraph (f) of this section, the operator of a pool plant or a cooperative association may divert the milk of a producer without limit.

(f) Diverted to a nonpool plant for the account of a handler operating a pool plant or for the account of a handler described in § 1036.9(c), subject to the following conditions:

(1) The operator of a pool plant may divert the milk of any producer that is not under the control of a cooperative association that diverts milk during the month pursuant to paragraph (f)(2) of this section. The operator of such plant may divert a total quantity of milk not exceeding 50 percent during the months of September through November, January and February, and 60 percent during the month of December, of the producer milk physically received at or diverted from such pool plant during the month;

(2) A cooperative association may divert an aggregate quantity of milk not exceeding 50 percent during the months of September through November, January and February, and 60 percent during the month of December, of the producer milk that the cooperative association caused to be physically received at or diverted from pool plants during the month;

(3) During each of the months of September through November not less than one day's production of a producer must be physically received at a pool plant;

(4) Milk of a producer shall not be eligible for diversion unless the milk of such producer has been physically received at least once as producer milk at a pool plant and the dairy farmer has

not been pooled on another federal order since that time;

(5) To the extent that it would result in nonpool plant status for the pool plant from which diverted, milk diverted for the account of a cooperative association from the pool plant of another handler shall not be deemed to have been received at such pool plant and shall not be producer milk;

(6) Any milk diverted in excess of the limit set forth in paragraph (f)(1) and (f)(2) of this section shall not be producer milk. The diverting handler shall designate the dairy farmer deliveries that shall not be producer milk. If the handler fails to do so, producer milk status shall be forfeited with respect to all milk diverted to nonpool plants by such handler; and

(7) Milk diverted to another order plant shall be producer milk only if a Class II or Class III classification is designated for such milk pursuant to the provisions of the other order issued pursuant to the Act and such milk is not subject to the pricing and pooling provisions of such order.

(g) [Reserved]

(h) Milk diverted pursuant to paragraphs (a)(3), (a)(4) and (b) of this section shall be deemed to have been received by the diverting handler at the location of the plant to which diverted.

3. Section 1036.30 is amended by revising paragraphs (a)(1)(i), (a)(3)(ii), (a)(4) and (b) to read as follows:

§ 1036.30 Reports of receipts and utilization.

(a) * * *

(1) * * *

(i) Producer milk, showing in the case of milk received directly from each producer the pounds of milk, the butterfat and milk protein contained in the milk, and the somatic cell count of the milk;

(3) * * *

(ii) Transfers and diversions to other plants, and the butterfat and milk protein content of such milk;

(4) Such other information with respect to the receipts and utilization of skim milk, butterfat and milk protein, and somatic cell count, as the market administrator may prescribe;

(b) Each cooperative association shall report:

(1) The quantities of skim milk, butterfat and milk protein, and somatic cell count contained in milk from producers for which it is the handler pursuant to § 1036.9 (b) or (c), showing:

(i) The quantity of milk delivered to each plant; and

(ii) For each producer the pounds of milk, butterfat and milk protein tests, and the somatic cell count;

(2) The utilization of all skim milk and butterfat required to be reported pursuant to paragraph (b)(1) of this section, except that contained in producer milk described in § 1036.13(b); and

(3) Such other information with respect to its receipts and utilization of skim milk, butterfat and protein, and somatic cell count as the market administrator may prescribe; and

4. Section 1036.31 is amended by revising paragraph (a)(2) and paragraph (b)(3) to read as follows:

§ 1036.31 Payroll reports.

(a) * * *

(2) The total pounds of milk, and, with respect to final payments, the average butterfat and protein content and somatic cell count of the milk for which payment is being made;

(b) * * *

(3) The average butterfat and milk protein content, and the somatic cell count, of such milk;

5. Section 1036.32 is amended by revising paragraph (c)(2) and paragraph (d) to read as follows:

§ 1036.32 Other reports.

(c) * * *

(2) The total pounds of producer milk received from such producer, its average butterfat and milk protein contents, and its average somatic count;

(d) On or before the second day prior to the reporting dates specified in paragraphs (a) and (c) of this section, each cooperative association that operates a pool plant from which bulk fluid milk products were transferred or diverted to pool plants of other handlers within the time periods described in paragraphs (a) and (c) of this section shall report to each such pool plant operator and the market administrator the name and location of the transferor-plant and the total pounds, butterfat and protein, and somatic cell count included in the bulk fluid milk products transferred or diverted from each such plant.

6. Section 1036.41 is amended by revising the second sentence of paragraph (c) to read as follows:

§ 1036.41 Shrinkage.

* * *

(c) * * * If the operator of the plant to which the milk is delivered purchases such milk on the basis of weights determined from its measurement at the farm, with protein and butterfat tests and somatic cell counts determined from farm bulk tank samples, the applicable percentage for the cooperative association shall be zero.

7. Section 1036.50 is amended by revising the section heading, revising the introductory language, and adding new paragraphs (d), (e) and (f), to read as follows:

§ 1036.50 Class and component prices.

Subject to the provisions of § 1036.52, the class and component prices for the month, per hundredweight or per pound, shall be as follows:

* * * * *

(d) *Butterfat price.* The butterfat price per pound shall be the total of the following steps, rounded to the nearest whole cent:

(1) The skim milk price per hundredweight for the month, computed pursuant to paragraph (f) of this section, divided by 100; and

(2) The butterfat differential for the month, computed pursuant to § 1036.74 multiplied by 10.

(e) *Milk protein price.* The price per pound for milk protein shall be computed by subtracting from the Class III price the butterfat price multiplied by 3.5, and dividing the result by the average protein content of the milk on which the basic formula price is based for the previous month as reported by the Department and adjusted for the current month by the Dairy Division, and rounding the result to the nearest whole cent.

(f) *Skim milk price.* The skim milk price per hundredweight shall be computed by subtracting from the Class III price the butterfat differential computed pursuant to § 1036.74 times 35, and rounding the result to the nearest whole cent.

8. Section 1036.53 is revised to read as follows:

§ 1036.53 Announcement of class and component prices.

The market administrator shall announce on or before:

- (a) The fifth day of each month:
- (1) The Class I price for the following month;
- (2) The Class III price for the preceding month;
- (3) The butterfat differential for the preceding month; and
- (4) The butterfat price, the milk protein price, and the skim milk price computed pursuant to § 1036.50 (d), (e) and (f) for the preceding month.

(5) The monthly average price for 40-pound blocks of cheese at the National Cheese Exchange (Green Bay, Wisconsin) for the preceding month.

(b) The 15th day of each month, the Class II price for the following month computed pursuant to § 1036.50(b).

9. The undesignated center heading before § 1036.60 is revised to read "DIFFERENTIAL POOL AND HANDLER OBLIGATIONS".

10. Section 1036.60 is revised to read as follows:

§ 1036.60 Computation of handlers' obligations to pool.

The market administrator shall compute each month for each handler defined in § 1036.9 (a), (b), and (c), an obligation to the pool computed by adding the following values:

(a) The pounds of producer milk in Class I as determined pursuant to § 1036.44 multiplied by the difference between the Class I price (adjusted pursuant to § 1036.52) and the Class III price;

(b) The pounds of producer milk in Class II as determined pursuant to § 1036.44 multiplied by the difference between the Class II price and the Class III price;

(c) The value of the product pounds, skim milk, and butterfat in overage assigned to each class pursuant to § 1036.44(a)(16) and the value of the corresponding protein pounds associated with the skim milk subtracted from Class II and Class III pursuant to § 1036.44(a)(16), by multiplying the skim milk pounds so assigned by the percentage of protein in the handler's receipts of producer skim milk during the month, as follows:

(1) The hundredweight of skim milk and butterfat subtracted from Class I pursuant to § 1036.44(a)(16) and the corresponding step of § 1036.44(b), multiplied by the difference between the Class I price adjusted for location and the Class III price, plus the hundredweight of skim milk subtracted from Class I pursuant to § 1036.44(a)(16) multiplied by the skim milk price, plus the butterfat pounds of overage subtracted from Class I pursuant to § 1036.44(b) multiplied by the butterfat price;

(2) The hundredweight of skim milk and butterfat subtracted from Class II pursuant to § 1036.44(a)(16) and the corresponding step of § 1036.44(b) multiplied by the difference between the Class II price and the Class III price, plus the protein pounds in skim milk subtracted from Class II pursuant to § 1036.44(a)(16) multiplied by the protein price, plus the butterfat pounds of overage subtracted from Class II

pursuant to § 1036.44(b) multiplied by the butterfat price;

(3) The protein pounds in skim milk overage subtracted from Class III pursuant to § 1036.44(a)(16) multiplied by the protein price, plus the butterfat pounds of overage subtracted from Class III pursuant to § 1036.44(b) multiplied by the butterfat price;

(d) The value of the product pounds, skim milk, and butterfat subtracted from Class I or Class II pursuant to § 1036.44(a)(9) and the corresponding step of § 1036.44(b), and the value of the protein pounds associated with the skim milk subtracted from Class II pursuant to § 1036.44(a)(9), computed by multiplying the skim milk pounds so subtracted by the percentage of protein in the handler's receipts of producer skim milk during the previous month, as follows:

(1) The value of the product pounds, skim milk and butterfat subtracted from Class I pursuant to § 1036.44(a)(9) and the corresponding step of § 1036.44(b) applicable at the location of the pool plant at the current month's Class I-Class III price difference and the current month's skim milk and butterfat prices, less the Class III value of the milk at the previous month's protein and butterfat prices;

(2) The value of the hundredweight of skim milk and butterfat subtracted from Class II pursuant to § 1036.44(a)(9) and the corresponding step of § 1036.44(b) at the current month's Class II-Class III price difference and the current month's protein and butterfat prices, less the Class III value of the milk at the previous month's protein and butterfat prices;

(e) The value of the product pounds, skim milk and butterfat subtracted from Class I pursuant to § 1036.44(a)(7)(i) through (iii), and the corresponding step of § 1036.44(b), excluding receipts of bulk fluid cream products from another order plant, applicable at the location of the pool plant at the current month's Class I-Class III price difference;

(f) The value of the product pounds, skim milk and butterfat subtracted from Class I pursuant to § 1036.44(a)(7) (iv) and (v) and the corresponding step of § 1036.44(b) applicable at the location of the transferor-plant at the current month's Class I-Class III price difference;

(g) The value of the product pounds, skim milk and butterfat subtracted from Class I pursuant to § 1036.44(a)(12) and the corresponding step of § 1036.44(b), excluding such hundredweight in receipts of bulk fluid milk products from an unregulated supply plant to the extent that an equivalent quantity disposed of to such plant by handlers

fully regulated by any Federal order is classified and priced as Class I milk and is not used as an offset for any other payment obligation under any order, applicable at the location of the nearest unregulated supply plants from which an equivalent volume was received at the current month's Class I-Class III price difference.

(h) The pounds of skim milk in Class I producer milk, as determined pursuant to § 1036.44 multiplied by the skim milk price for the month computed pursuant to § 1036.50(f).

(i) The pounds of protein in skim milk in Class II and Class III, computed by multiplying the skim milk pounds so assigned by the percentage of protein in the handler's receipts of producer skim milk during the month for each report filed, separately, multiplied by the protein price for the month computed pursuant to § 1036.50(e) and adjusted pursuant to § 1036.66 for the weighted average somatic cell content of the handler's receipts of milk.

(j) The pounds of butterfat in all three classes as determined pursuant to § 1036.44 multiplied by the butterfat price for the month computed pursuant to § 1036.50(d).

(k) Subtract, for reconstituted milk made from receipts of nonfluid milk products, an amount computed by multiplying \$1.00 (but not more than the difference between the Class I price applicable at the location of the pool plant and the Class III price) by the hundredweight of skim milk and butterfat contained in receipts of nonfluid milk products that are allocated to Class I use, provided that the handler establishes a disposition of labeled reconstituted fluid milk products; and

(l) Exclude, for pricing purposes under this section, receipts of nonfluid milk products that are distributed as labeled reconstituted milk for which payments are made to the producer-settlement fund of another order under § 1036.76(c).

11. Section 1036.61 is revised to read as follows: § 1036.61 Computation of weighted average differential value.

For each month the market administrator shall compute the weighted average differential value for milk received from all producers as follows:

(a) Combine into one total the values computed pursuant to § 1036.60, paragraphs (a) through (g) and (k) and

(l), for all handlers who made reports pursuant to § 1036.30 and who made payments pursuant to § 1036.71 for the preceding month;

(b) Add an amount equal to the total value of the minus location adjustments computed pursuant to § 1036.75(a);

(c) Subtract an amount equal to the total value of the plus location differentials computed pursuant to § 1036.75(a);

(d) Add an amount equal to not less than one-half the unobligated balance in the producer-settlement fund;

(e) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(1) The total hundredweight of producer milk; and

(2) The total hundredweight for which a value is computed pursuant to § 1036.60(g).

(f) Subtract not less than 4 cents nor more than 5 cents per hundredweight. The result shall be the "Weighted Average Differential Price".

12. Section 1036.62 is revised to read as follows:

§ 1036.62 Computation of producer protein price.

For each month the market administrator shall compute the producer protein price to be paid to all producers for the pounds of protein in their milk, as follows:

(a) Combine into one total the values computed pursuant to § 1036.60, paragraphs (h) and (i), for all handlers who made reports pursuant to § 1036.30 and who made payments pursuant to § 1036.71 for the preceding month;

(b) Add all of the negative adjustments and subtract all of the positive adjustments determined for each producer's somatic cell count pursuant to § 1036.66;

(c) Divide the resulting amount by the total pounds of protein in producer milk; and

(d) Round to the nearest whole cent. The result is the "Producer protein price."

13. New §§ 1036.63 through 1036.66 are added under the undesignated center heading "Differential Pool and Handler Obligations" to read as follows:

§ 1036.63 Uniform price and handlers' obligations for producer milk.

(a) A uniform price for producer milk containing 3.5 percent butterfat shall be computed by adding the weighted average differential price determined

pursuant to § 1036.61 to the basic formula price for the month.

(b) Handler obligations to producers and cooperative associations for producer milk shall be determined in accordance with the provisions of §§ 1036.65 and 1036.73.

§ 1036.64 Announcement of weighted average differential price, producer protein price, and uniform price.

The market administrator shall announce publicly on or before the 13th day after the end of the month the weighted average differential price computed pursuant to § 1036.61, the producer protein price computed pursuant to § 1036.62, and the uniform price computed pursuant to § 1036.63(a).

§ 1036.65 Value of producer milk.

The value of producer milk shall be the sum of:

(a) The weighted average differential price computed pursuant to § 1036.61 and adjusted pursuant to § 1036.75, multiplied by the total hundredweight of producer milk received from the producer;

(b) The producer protein price computed pursuant to § 1036.62 and adjusted pursuant to § 1036.66, multiplied by the total milk protein contained in the producer milk received from the producer; and

(c) The butterfat price computed pursuant to § 1036.50(d) multiplied by the total butterfat contained in the producer milk received from the producer.

§ 1036.66 Computation of somatic cell adjustment.

(a) For each producer, an adjustment to the producer protein price for the somatic cell count of the producer's milk shall be determined by multiplying the constant associated with the appropriate somatic cell count interval in the table in paragraph (b) of this section by the average price for the month of 40-pound blocks of cheese at the National Cheese Exchange at Green Bay, WI, as reported monthly by the Dairy Division, Agricultural Marketing Service. If a handler has not determined a monthly average somatic cell count, it will be determined by the market administrator.

(b) The following table shows the factors and constants to be used in computing the somatic cell adjustment.

FACTORS AND CONSTANTS TO BE USED IN COMPUTING THE SOMATIC CELL ADJUSTMENT

Somatic cell counts	Factors	Constants for computing the somatic cell adjustment
1 to 50,000	.300	.09375
51,000 to 100,000	.200	.062500
101,000 to 150,000	.150	.046875
151,000 to 200,000	.100	.031250
201,000 to 250,000	.050	.015625
251,000 to 300,000	.025	.0078125
301,000 to 350,000	.000	.000000
351,000 to 400,000	.000	.000000
401,000 to 450,000	-.025	-.0078125
451,000 to 500,000	-.050	-.015625
501,000 to 550,000	-.075	-.0234375
551,000 to 600,000	-.100	-.031250
601,000 to 650,000	-.125	-.0390625
651,000 to 700,000	-.150	-.046875
701,000 to 750,000	-.200	-.062500
751,000 and above	-.250	-.078125

14. Section 1036.71 is amended by revising the introductory language of paragraph (b), paragraph (b)(1), and paragraph (c) to read as follows:

§ 1036.71 Payments to the market administrator.

(b) Subject to paragraph (d) of this section, each handler shall pay to the market administrator on or before the 17th day after the end of each month the value of such handler's milk pursuant to § 1036.60(a) through (l), less:

(1) The amount obtained from multiplying the weighted average differential price applicable at the location of the plants from which the other source milk is received (not to be less than zero) by the hundredweight of other source milk for which a value is computed pursuant to § 1036.60(g);

(c) Subject to paragraph (d) of this section, each handler operating a pool plant who receives bulk fluid milk products by transfer or diversion from a pool plant operated by a cooperative association, or who receives milk from a cooperative association in its capacity as a handler pursuant to § 1036.9(c) that also operates a pool plant, shall pay to the market administrator, on or before the 17th day after the end of each month, an amount determined by the sum of the following:

(1) The quantity of such receipts classified as Class I pursuant to § 1036.44(a)(15) and the corresponding step of § 1036.44(b) multiplied by the difference between the Class I price (adjusted pursuant to § 1036.44(a)(15) and the corresponding step of § 1036.44(b) multiplied by the difference between the Class I price at

the receiving plant (adjusted pursuant to § 1036.52) and the Class III price;

(2) The quantity of such receipts classified as Class II pursuant to § 1036.44(a)(15) and the corresponding step of § 1036.44(b) multiplied by the difference between the Class II price and the Class III price;

(3) The quantity of skim milk in such receipts classified as Class I pursuant to § 1036.44(a)(15) multiplied by the skim milk price for the month computed pursuant to § 1036.50(f);

(4) The pounds of protein in the skim milk in such receipts classified in Class II and Class III, computed by multiplying the skim milk pounds so assigned by the percentage of protein in the handler's receipts of skim milk from a pool plant operated by a cooperative association, or from a cooperative association in its capacity as a handler pursuant to § 1036.9(c);

(5) The pounds of butterfat in all three classes as determined pursuant to § 1036.44(b)(15) multiplied by the butterfat price for the month computed pursuant to § 1036.50(d); less

(6) Any payments made by the handler pursuant to paragraphs (a)(2) and (a)(3) of this section for such month.

15. Section 1036.72 is revised to read as follows:

§ 1036.72 Payments from the producer-settlement fund.

Subject to § 1036.73(c), on or before the 18th day after the end of each month, the market administrator shall pay to each handler the amount, if any, by which the net pool obligation pursuant to § 1036.60 for such handler is less than the value of such handler's receipts of producer milk at the weighted average differential price

adjusted pursuant for location pursuant to § 1036.75, the protein price before adjustments are made for somatic cell count, and the butterfat price.

16. Section 1036.73 is amended by revising paragraphs (a)(2) introductory text, (b)(2), (d)(2) and (d)(3) to read as follows:

§ 1036.73 Payments to producers and to cooperative associations.

(a) * * *

(2) On or before the 18th day after the end of the month, to each producer not less than the value determined pursuant to § 1036.65, less the following amounts:

(b) * * *

(2) On or before the 18th day after the end of each month for milk for which payment is received by the market administrator pursuant to § 1036.71. Such payment shall be in the amount determined for such milk pursuant to § 1036.65, less the payments made pursuant to paragraph (b)(1) of this section.

(d) * * *

(2) The total pounds and, with respect to final payments, the average butterfat and milk protein content and somatic cell count of the milk for which payment is being made;

(3) The minimum rates of payment required by the order and the rates of payment used if such rates are other than the applicable minimum rates;

§ 1036.85 [Amended]

17. Section 1036.85 is amended by changing the words "3 cents" in the introductory language to "4 cents".

§ 1036.86 [Amended]

18. Section 1036.86 is amended by changing the words "5 cents" in paragraph (a) to "7 cents".

PART 1049—MILK IN THE INDIANA MARKETING AREA

1. Section 1049.3 is revised to read as follows:

§ 1049.3 Route disposition.

Route disposition means a delivery (including that packaged for another person, another distributing plant, disposition from a plant store or from a distribution point, and distribution by a vendor or vending machine) of any packaged fluid milk product classified as Class I milk other than a delivery in bulk form to any milk or filled milk processing plant.

2. Section 1049.6 is revised to read as follows:

§ 1049.6 Supply plant.

Supply plant means a plant in which some milk approved by any duly constituted health authority for fluid consumption in the marketing area is assembled and shipped in bulk as a fluid milk product and is physically unloaded and received into a distributing plant during the month.

3. Section 1049.7 is amended by revising paragraphs (a) and (b), redesignating present paragraph (c) as paragraph (d), and adding a new paragraph (c), to read as follows:

§ 1049.7 Pool plant.

(a) A distributing plant with:

(1) Total route disposition of not less than 40 percent during each of the months of September through February, 35 percent during each of the months of March through July, and 30 percent during the month of August, of its total receipts of fluid milk products (including milk diverted from such plant but excluding bulk fluid milk products received by transfer or diversion from other plants as Class II or Class III milk) that are approved by a duly constituted health authority for fluid consumption, subject to the following conditions:

(i) In making the percentage computations in paragraphs (a) (1) and (2) of this section, a plant's route disposition and receipts shall be exclusive of filled milk and of packaged fluid milk products received from other pool or other Federal order plants;

(ii) A plant meeting such percentage requirement for the two immediately preceding months and the requirement of paragraph (a)(2) of this section for the current month may remain qualified

under this paragraph in the current month; and

(iii) A plant meeting the requirements of this paragraph in each of the months of September through May, inclusive, shall continue to have pool plant status in the months of June and July immediately following if the plant meets the requirements of paragraph (a)(2) of this section;

(2) Route disposition within the marketing area during the month of at least 10 percent of such receipts, such route disposition to be exclusive of packaged fluid milk products received from other plants and filled milk.

(b) A supply plant from which not less than 40 percent during the months of September through February and not less than 35 percent during the months of March through August, of the Grade A milk received from producers (including producer milk diverted from the plant but excluding milk diverted to such plant) and from handlers described in § 1049.9(c) at such plant during the month is shipped to plants qualifying for the month pursuant to paragraph (a) of this section. A plant qualified pursuant to this paragraph in each of the immediately preceding months of September through February shall remain so qualified for the months of April through August unless written application is filed with the market administrator on or before the first day of any such month to designate such plant as a nonpool plant for such month and for each subsequent month through August during which it would otherwise not qualify under this paragraph. Pool supply plant qualification shall be subject to the following conditions:

(1) The operator of a supply plant may include milk diverted from such plant to pool distributing plants as qualifying deliveries in meeting up to one-half of the required deliveries;

(2) Shipments to be used in determining qualifying percentages shall be milk transferred or diverted and physically received by distributing pool plants, less any transfers or diversions of bulk fluid milk products from such distributing pool plants; and

(3) The shipping percentage requirements of this paragraph may be increased or decreased temporarily by up to 10 percentage points by the market administrator if such person finds that such revision is necessary to obtain needed shipments or to prevent uneconomic shipments. Before making such a finding, the market administrator shall investigate the need for revision on either such person's own initiative or at the request of interested persons. If the investigation shows that a temporary

revision might be appropriate, the market administrator shall issue a notice stating that revision is being considered and invite data, views, or arguments in favor of or in opposition to the proposed temporary revision.

(c) Any plant that qualifies as a pool plant in each of the immediately preceding three months pursuant to paragraph (a) of this section or by meeting the shipping percentages in paragraph (b) of this section that is unable to meet such performance standards for the current month because of unavoidable circumstances determined by the market administrator to be beyond the control of the handler operating the plant, such as a natural disaster (ice storm, wind storm, flood) fire, breakdown of equipment, or work stoppage, shall be considered to have met the minimum performance standards during the period of such unavoidable circumstances, but such relief shall not be granted for more than two consecutive months.

4. Section 1049.13 is revised to read as follows:

§ 1049.13 Producer milk.

Producer milk means the skim milk and butterfat contained in milk from producers which is:

(a) Received at a pool plant directly from a producer, excluding any such milk received by diversion from another pool plant;

(b) Received at a pool plant from a handler described in § 1049.9(c) under the conditions set forth therein;

(c) Received by a handler described in § 1049.9(c) from producers in excess of the quantity delivered to pool plants;

(d) Diverted from a pool plant for the account of the handler operating such plant to another pool plant; or

(e) Diverted from a pool plant to a nonpool plant (other than a producer-handler plant) for the account of the handler operating such pool plant or for the account of a handler described in § 1049.9(b), subject to the following conditions:

(1) During each of the months of September through November not less than one day's production of the producer must be physically received at a pool plant;

(2) The operator of a pool plant may divert the milk of any producer that is not under the control of a cooperative association that diverts milk during the month pursuant to paragraph (e)(3) of this section. The operator of such plant may divert a total quantity of milk not exceeding 50 percent during the months of September through November, January and February, and 60 percent

during the month of December, of the producer milk physically received at or diverted from such pool plant during the month;

(3) A cooperative association may divert an aggregate quantity of milk not exceeding 50 percent during the months of September through November, January and February, and 60 percent during the month of December, of the producer milk that the cooperative association caused to be physically received at or diverted from pool plants during the month;

(4) Any milk diverted in excess of the limit set forth in paragraph (e)(2) or (3) of this section shall not be producer milk. The diverting handler shall designate the dairy farmer deliveries that shall not be producer milk. If the handler fails to designate the dairy farmer deliveries which are ineligible, producer milk status shall be forfeited with respect to all milk diverted to nonpool plants by such handler; and

(f) Milk diverted pursuant to paragraph (d) or (e) of this section shall be priced at the location of the plant where it is received, except that the uniform price applicable to milk that is diverted to a plant located outside the areas specified in § 1049.52(a)(1) through (3) shall not be adjusted downward below the uniform price for the month applicable at the location of the producer's farm, *Provided*, that 65 percent or more of such producer's milk is delivered to a plant or plants in an area specified in § 1049.52(a)(1) through (3) or to a plant at which the same or a higher uniform price is applicable.

5. Section 1049.30 is amended by revising paragraphs (a)(1), (a)(6), and (c), to read as follows:

§ 1049.30 Reports of receipts and utilization.

* * * * *

(a) * * *

(1) Receipts of producer milk, including producer milk diverted by the handler from the pool plant to other plants, showing the pounds of milk, butterfat and milk protein contained in the milk, and the somatic cell count of the milk;

* * * * *

(6) The utilization or disposition of all skim milk and butterfat required to be reported pursuant to this paragraph, showing separately:

(i) Total route dispositions and route disposition in the marketing area, showing separately such disposition of filled milk inside and outside the marketing area; and

(ii) Transfers and diversions to other plants, the butterfat and milk protein

content of such milk, and the somatic cell count of the milk;

(b) * * *

(c) Each cooperative association shall report:

(1) The quantities of skim milk, butterfat and milk protein, and somatic cell count contained in milk from producers for which it is the handler pursuant to § 1049.9 (b) or (c), showing:

(i) The quantities of such receipts delivered to each pool plant of other handlers; and

(ii) The classification of such receipts diverted pursuant to § 1049.13.

(2) [Reserved]

(d) * * *

6. Section 1049.31 is amended by revising paragraphs (a)(3) and (a)(4) to read as follows:

§ 1049.31 Payroll reports.

(a) * * *

(3) The average butterfat content, average milk protein content, and average somatic cell count of such milk; and

(4) The price per hundredweight, butterfat and milk protein prices and somatic cell adjustment to the producer protein price, the gross amount due, the amount and nature of any deductions, and the net amount paid.

* * * * *

7. Section 1049.32 is amended by removing paragraph (a) and the paragraph designation from paragraph (b), and deleting the words "paragraph (a) of this section and".

8. Section 1049.41 is amended by revising the second sentence of paragraph (c) to read as follows:

§ 1049.41 Shrinkage.

* * * * *

(c) * * * If the operator of the plant to which the milk is delivered purchases such milk on the basis of weights determined from its measurement at the farm, with protein and butterfat tests and somatic cell counts determined from farm bulk tank samples, the applicable percentage for the cooperative association shall be zero.

9. Section 1049.50 is amended by revising the section heading, revising the introductory language and paragraph (a), and adding new paragraphs (d), (e) and (f), to read as follows:

§ 1049.50 Class and component prices.

Subject to the provisions of § 1049.52, the class and component prices for the month, per hundredweight or per pound, shall be as follows:

(a) The Class I price shall be the basic formula price for the second preceding month plus \$1.90.

* * * * *

(d) *Butterfat price.* The butterfat price per pound shall be the total of the following steps, rounded to the nearest whole cent:

(1) The skim milk price per hundredweight for the month, computed pursuant to paragraph (f) of this section, divided by 100; and

(2) The butterfat differential for the month, computed pursuant to § 1049.74 multiplied by 10.

(e) *Milk protein price.* The price per pound for milk protein shall be computed by subtracting from the Class III price the butterfat price multiplied by 3.5, and dividing the result by the average protein content of the milk on which the basic formula price is based for the previous month as reported by the Department and adjusted for the current month by the Dairy Division, and rounding the result to the nearest whole cent.

(f) *Skim milk price.* The skim milk price per hundredweight shall be computed by subtracting from the Class III price the butterfat differential, computed pursuant to § 1049.74 times 35, and rounding the result to the nearest whole cent.

10. Paragraphs (a) and (b) of § 1049.52 are revised to read as follows:

§ 1049.52 Plant location adjustments for handlers.

(a) For producer milk received at pool plants located in the following zones, which milk is classified as Class I milk or assigned Class I location adjustment credit pursuant to paragraph (b) of this section, the price computed pursuant to § 1049.50(a) shall be adjusted as set forth in paragraphs (a)(1) through (a)(7), as follows, except that in no event shall the adjustment result in a price less than the Class III price for the month:

(1) *Zero adjustment zone.* Any Indiana county not specifically named in paragraphs (a)(2) through (a)(5) of this section, and not part of the Louisville-Lexington-Evansville marketing area.

(2) *Plus 10-cent adjustment zone.* The Indiana counties of Jackson, Jefferson, Jennings, Lawrence, Ripley, Scott and Switzerland.

(3) *Minus 10-cent adjustment zone.* The Indiana counties of Adams, Allen, Benton, Blackford, Carroll, Cass, Fulton, Huntington, Jay, Miami, Wabash, Wells, and White.

(4) *Minus 20-cent adjustment zone.* The Indiana counties of Dekalb, Elkhart, Jasper, Kosciusko, Lagrange, La Porte, Marshall, Newton, Noble, Pulaski, Starke, Steuben, St. Joseph, and

Whitley; and the Michigan counties of Berrien, Branch, Cass and St. Joseph.

(5) *Minus 35-cent adjustment zone.* The Indiana counties of Lake and Porter.

(6) At locations in other Federal order marketing areas, the appropriate price adjustment shall be the difference between the applicable Class I price effective at such plant location under the order for the area in which the plant is located and the Class I price specified in § 1049.50(a). For purposes of this paragraph, the locations in the Ohio counties of Defiance, Paulding, Van Wert and Williams, and the Michigan counties of Hillsdale, Lenawee and Monroe that are not part of any Federal milk order marketing area, will be considered to be in pricing zone 1 of the Ohio Valley milk marketing area.

(7) At locations outside any Federal order marketing area and north of 38 degrees latitude, the applicable adjustment rate per hundredweight shall be based on the shortest highway distance between the plant and the nearest of the Monument Circle, Indianapolis, Indiana, or the main post offices of Fort Wayne, South Bend, or Valparaiso, Indiana, and shall be minus 2.0 cents for each 10 miles or fraction thereof from such point in addition to the amount of the location adjustment pursuant to paragraphs (a) (1) through (5) of this section applicable at the respective point.

(b) For the purpose of calculating adjustments pursuant to this section, transfers between pool plants shall be assigned Class I disposition at the transferee-plant, in excess of the receipts at such plant from producers and handlers pursuant to § 1049.9 (b) and (c) and the volume assigned as Class I to receipts from other order plants and unregulated supply plants, such assignment to be made first to transferor-plants at which the Class I price is not less than the Class I price at the transferee plant, and then to receipts from plants with lower Class I prices in sequence beginning with the plant having the highest Class I price.

11. Section 1049.53 is revised to read as follows:

§ 1049.53 Announcement of class and component prices.

The market administrator shall announce on or before:

- (a) The fifth day of each month:
- (1) The Class I price for the following month;
- (2) The Class III price for the preceding month;
- (3) The butterfat differential for the preceding month; and

(4) The butterfat price, the milk protein price, and the skim milk price computed pursuant to § 1049.50(d), (e) and (f) for the preceding month.

(5) The monthly average price for 40-pound blocks of cheese at the National Cheese Exchange (Green Bay, Wisconsin) for the preceding month.

(b) The 15th day of each month, the Class II price for the following month computed pursuant to § 1049.50(b).

12. The undesignated center heading before § 1049.60 is revised to read

"Differential Pool and Handler Obligations"

13. Section 1049.60 is revised to read as follows:

§ 1049.60 Computation of handlers' obligations to pool.

The market administrator shall compute each month for each pool plant of each handler, and for each handler pursuant to § 1049.9 (b) and (c), an obligation to the pool computed by adding the following values:

(a) The pounds of producer milk in Class I as determined pursuant to § 1049.44 multiplied by the difference between the Class I price (adjusted pursuant to § 1049.52) and the Class III price;

(b) The pounds of producer milk in Class II as determined pursuant to § 1049.44 multiplied by the difference between the Class II price and the Class III price;

(c) The value of the product pounds, skim milk, and butterfat in overage assigned to each class pursuant to § 1049.44(a)(14) and the value of the corresponding protein pounds associated with the skim milk subtracted from Class II and Class III pursuant to § 1049.44(a)(14), by multiplying the skim milk pounds so assigned by the percentage of protein in the handler's receipts of producer skim milk during the month, as follows:

(1) The hundredweight of skim milk and butterfat subtracted from Class I pursuant to § 1049.44(a)(14) and the corresponding step of § 1049.44(b), multiplied by the difference between the Class I price adjusted for location and the Class III price, plus the hundredweight of skim milk subtracted from Class I pursuant to § 1049.44(a)(14) multiplied by the skim milk price, plus the butterfat pounds of overage subtracted from Class I pursuant to § 1049.44(b) multiplied by the butterfat price;

(2) The hundredweight of skim milk and butterfat subtracted from Class II pursuant to § 1049.44(a)(14) and the corresponding step of § 1049.44(b) multiplied by the difference between

the Class II price and the Class III price, plus the protein pounds in skim milk subtracted from Class II pursuant to § 1049.44(a)(14) multiplied by the protein price, plus the butterfat pounds of overage subtracted from Class II pursuant to § 1049.44(b) multiplied by the butterfat price;

(3) The protein pounds in skim milk overage subtracted from Class III pursuant to § 1049.44(a)(14) multiplied by the protein price, plus the butterfat pounds of overage subtracted from Class III pursuant to § 1049.44(b) multiplied by the butterfat price;

(d) The value of the product pounds, skim milk, and butterfat subtracted from Class I or Class II pursuant to § 1049.44(a)(9) and the corresponding step of § 1049.44(b), and the value of the protein pounds associated with the skim milk subtracted from Class II pursuant to § 1049.44(a)(9), computed by multiplying the skim milk pounds so subtracted by the percentage of protein in the handler's receipts of producer skim milk during the previous month, as follows:

(1) The value of the product pounds, skim milk and butterfat subtracted from Class I pursuant to § 1049.44(a)(9) and the corresponding step of § 1049.44(b) applicable at the location of the pool plant at the current month's Class I-Class III price difference and the current month's skim milk and butterfat prices, less the Class III value of the milk at the previous month's protein and butterfat prices;

(2) The value of the hundredweight of skim milk and butterfat subtracted from Class II pursuant to § 1049.44(a)(9) and the corresponding step of § 1049.44(b) at the current month's Class II-Class III price difference and the current month's protein and butterfat prices, less the Class III value of the milk at the previous month's protein and butterfat prices;

(e) The value of the product pounds, skim milk and butterfat subtracted from Class I pursuant to § 1049.44(a)(7) (i) through (iv), and the corresponding step of § 1049.44(b), excluding receipts of bulk fluid cream products from another order plant, applicable at the location of the pool plant at the current month's Class I-Class III price difference;

(f) The value of the product pounds, skim milk and butterfat subtracted from Class I pursuant to § 1049.44(a)(7) (v) and (vi) and the corresponding step of § 1049.44(b) applicable at the location of the transferor-plant at the current month's Class I-Class III price difference;

(g) The value of the product pounds, skim milk and butterfat subtracted from Class I pursuant to § 1049.44(a)(11) and

the corresponding step of § 1049.44(b), excluding such hundredweight in receipts of bulk fluid milk products from an unregulated supply plant to the extent that an equivalent quantity disposed of to such plant by handlers fully regulated by any Federal order is classified and priced as Class I milk and is not used as an offset for any other payment obligation under any order, applicable at the location of the nearest unregulated supply plants from which an equivalent volume was received at the current month's Class I-Class III price difference.

(h) The pounds of skim milk in Class I producer milk, as determined pursuant to § 1049.44 multiplied by the skim milk price for the month computed pursuant to § 1049.50(f).

(i) The pounds of protein in skim milk in Class II and Class III, computed by multiplying the skim milk pounds so assigned by the percentage of protein in the handler's receipts of producer skim milk during the month for each report filed, separately, multiplied by the protein price for the month computed pursuant to § 1049.50(e) and adjusted pursuant to § 1049.66 for the weighted average somatic cell content of the handler's receipts of milk.

(j) Subtract, for reconstituted milk made from receipts of nonfluid milk products, an amount computed by multiplying \$1.00 (but not more than the difference between the Class I price applicable at the location of the pool plant and the Class III price) by the hundredweight of skim milk and butterfat contained in receipts of nonfluid milk products that are allocated to Class I use, provided that the handler establishes a disposition of labeled reconstituted fluid milk products; and

(k) Exclude, for pricing purposes under this section, receipts of nonfluid milk products that are distributed as labeled reconstituted milk for which payments are made to the producer-settlement fund of another order under § 1049.76(c).

14. Section 1049.61 is revised to read as follows:

§ 1049.61 Computation of weighted average differential value.

For each month the market administrator shall compute the weighted average differential value for milk received from all producers as follows:

(a) Combine into one total the values computed pursuant to § 1049.60,

paragraphs (a) through (g) and (j) and (k), for all handlers who made reports pursuant to § 1049.30 and who made payments pursuant to § 1049.71 for the preceding month;

(b) Add an amount equal to the total value of the minus location adjustments computed pursuant to § 1049.75(a);

(c) Subtract an amount equal to the total value of the plus location differentials computed pursuant to § 1049.75(a);

(d) Add an amount equal to not less than one-half the unobligated balance in the producer-settlement fund;

(e) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(1) The total hundredweight of producer milk; and

(2) The total hundredweight for which a value is computed pursuant to § 1049.60(g).

(f) Subtract not less than 4 cents nor more than 5 cents per hundredweight. The result shall be the "Weighted Average Differential Price";

15. Section 1049.62 is revised to read as follows:

§ 1049.62 Computation of producer protein price.

For each month the market administrator shall compute the producer protein price to be paid to all producers for the pounds of protein in their milk, as follows:

(a) Combine into one total the values computed pursuant to § 1049.60, paragraphs (h) and (i), for all handlers who made reports pursuant to § 1049.30 and who made payments pursuant to § 1049.71 for the preceding month;

(b) Add all of the negative adjustments and subtract all of the positive adjustments determined for each producer's somatic cell count pursuant to § 1049.66;

(c) Divide the resulting amount by the total pounds of protein in producer milk; and

(d) Round to the nearest whole cent. The result is the "Producer protein price."

16. New §§ 1049.63 through 1049.66 are added under the undesignated center heading "DIFFERENTIAL POOL AND HANDLER OBLIGATIONS:" to read as follows:

§ 1049.63 Uniform price and handlers' obligations for producer milk.

(a) A uniform price for producer milk containing 3.5 percent butterfat shall be computed by adding the weighted

average differential price determined pursuant to § 1049.61 to the basic formula price for the month.

(b) Handler obligations to producers and cooperative associations for producer milk shall be determined in accordance with the provisions of §§ 1049.65 and 1049.73.

§ 1049.64 Announcement of weighted average differential price, producer protein price, and uniform price.

The market administrator shall announce publicly on or before the 14th day after the end of the month the weighted average differential price computed pursuant to § 1049.61, the producer protein price computed pursuant to § 1049.62, and the uniform price computed pursuant to § 1049.63(a).

§ 1049.65 Value of producer milk.

The value of producer milk shall be the sum of:

(a) The weighted average differential price computed pursuant to § 1049.61 and adjusted pursuant to § 1049.75, multiplied by the total hundredweight of producer milk received from the producer;

(b) The producer protein price computed pursuant to § 1049.62 and adjusted pursuant to § 1049.66, multiplied by the total milk protein contained in the producer milk received from the producer; and

(c) The butterfat price computed pursuant to § 1049.50(d) multiplied by the total butterfat contained in the producer milk received from the producer.

§ 1049.66 Computation of somatic cell adjustment.

(a) For each producer, an adjustment to the producer protein price for the somatic cell count of the producer's milk shall be determined by multiplying the constant associated with the appropriate somatic cell count interval in the table in paragraph (b) of this section by the average price for the month of 40-pound blocks of cheese at the National Cheese Exchange at Green Bay, WI, as reported monthly by the Dairy Division, Agricultural Marketing Service. If a handler has not determined a monthly average somatic cell count, it will be determined by the market administrator.

(b) The following table shows the factors and constants to be used in computing the somatic cell adjustment.

FACTORS AND CONSTANTS TO BE USED IN COMPUTING THE SOMATIC CELL ADJUSTMENT

Somatic cell counts	Factors	Constants for Computing the Somatic cell adjustment
1 to 50,000	.300	.09375
51,000 to 100,000	.200	.062500
101,000 to 150,000	.150	.046875
151,000 to 200,000	.100	.031250
201,000 to 250,000	.050	.015625
251,000 to 300,000	.025	.0078125
301,000 to 350,000	.000	.000000
351,000 to 400,000	.000	.000000
401,000 to 450,000	-.025	-.0078125
451,000 to 500,000	-.050	-.015625
501,000 to 550,000	-.075	-.0234375
551,000 to 600,000	-.100	-.031250
601,000 to 650,000	-.125	-.0390625
651,000 to 700,000	-.150	-.046875
701,000 to 750,000	-.200	-.062500
751,000 and above	-.250	-.078125

17. Section 1049.71 is amended by revising paragraphs (a)(1) and (a)(2) to read as follows:

§ 1049.71 Payments to the producer settlement fund.

(a) * * *

(1) The total obligation of the handler for such month as determined pursuant to § 1049.60.

(2) The sum of:

(i) The value of such handler's receipts of producer milk at the weighted average differential price adjusted pursuant to § 1049.75;

(ii) The value of the protein in such handler's receipts of producer milk at the producer protein price computed pursuant to § 1049.62; and

(iii) The value at the weighted average differential price applicable at the location of the plant from which received of other source milk for which a value is computed pursuant to § 1049.60(g).

* * *

18. Section 1049.73 is amended by revising the first sentence of paragraph (a)(2), paragraph (c)(2)(ii), and paragraph (d)(2) to read as follows:

§ 1049.73 Payments to producers and to cooperative associations.

(a) * * *

(2) On or before the 18th day after the end of the month to each producer, not less than the value determined pursuant to § 1049.65, less any payment made pursuant to paragraph (a)(1) of this section, and less the deduction for advertising and promotion made pursuant to § 1049.107. * * *

* * *

(c) * * *

(2) * * *

(ii) On or before the 16th day of the following month for milk received during the month, not less than the value of milk determined pursuant to § 1049.65, less any payments made pursuant to paragraph (c)(2)(i) of this section.

(d) * * *

(2) The daily and total pounds of producer milk, its butterfat and milk protein content, and the somatic cell count of the milk;

* * *

19. Section 1049.75 is revised to read as follows:

§ 1049.75 Plant location adjustments for producers and on nonpool milk.

(a) The weighted average differential price for producer milk received at pool plants or diverted to nonpool plants shall be adjusted according to the location of the plants at which it was received or was deemed to have been received at the rates set forth in § 1049.52(a), except that the adjusted weighted average differential price plus the withholding rate for the Advertising and Promotion program computed in § 1049.121(e), shall be not less than zero for the month.

(b) For purposes of computations pursuant to §§ 1049.71 and 1049.72 the weighted average differential price shall be adjusted at the rates set forth in § 1049.52 applicable at the location of the nonpool plant from which the milk was received, except that the adjusted weighted average differential price shall not be less than zero.

20. Section 1049.78 is revised to read as follows:

§ 1049.78 Charges on overdue accounts.

(a) Any unpaid obligation of a handler pursuant to § 1049.71, § 1049.76,

§ 1049.77(a), § 1049.78, § 1049.85, or § 1049.86(a) shall be increased 1 percent beginning on the first day after the due date of such obligation and on the same day of each succeeding month until such obligation is paid. All such charges on overdue accounts shall be paid to the administrative assessment fund maintained by the market administrator.

(b) Any obligation that was determined at a date later than that prescribed by the order because of a handler's failure to submit a report to the market administrator when due, shall be considered to have been payable by the date it would have been due if the report had been filed when due.

§ 1049.86 [Amended]

21. Section 1049.86 is amended by changing the words "5 cents" in paragraph (a) to "7 cents."

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 orders regulating the handling of milk in the Ohio Valley, Eastern Ohio-Western Pennsylvania and Indiana marketing areas (7 CFR PARTS 1033, 1036 and 1049) which is annexed hereto; and

II. The following provisions:

¹ First and last sections of order.

§ ____² Record of milk handled and authorization to correct typographical errors.
(a) Record of milk handled. The undersigned certifies that he handled during the month of October 1992, ____ 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.

§ ____² 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)

(Seal)

BY

(Name)

(Title)

(Address)

Attest

[FR Doc. 93-14036 Filed 6-16-93; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 32, and 35

RIN 3150-AD69

Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations for the medical use of byproduct material. This action is being taken in response to a petition for rulemaking. The proposed rule is intended to provide greater flexibility by allowing properly qualified nuclear pharmacists and authorized users who are physicians greater discretion to prepare radioactive drugs containing byproduct material for medical use. The proposed rule would also allow research involving human subjects using byproduct material and the medical use of radiolabeled biologics. In addition, the proposed rule also contains other miscellaneous and conforming

amendments necessary to clarify or update the current regulations.

DATES: The comment period expires October 15, 1993. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Mail written comments to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m., and 4:15 p.m. on Federal workdays.

Copies of the draft regulatory analysis and any public comments received on the proposed rule may be examined at: the NRC Public Document Room, 2120 L Street, NW, (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Samuel Z. Jones or Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3738 for Mr. Jones, or (301) 492-3797 for Mr. Tse.

SUPPLEMENTARY INFORMATION:

Background

The Petition for Rulemaking

In early 1989, the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) approached the NRC staff with concerns that the Commission's regulations failed to accommodate the functions and responsibilities of the practice of nuclear pharmacy. At the suggestion of the NRC staff, the ACNP and SNM submitted a petition for rulemaking requesting the Commission to amend its regulations to fully recognize the role of licensed nuclear pharmacists and physicians. On September 15, 1989 (54 FR 38239), the Commission published in the *Federal Register* a notice of receipt of a petition for rulemaking for public comment (PRM-35-9).

During the development of the ACNP-SNM petition, one NRC staff member provided substantial assistance in the preparation of the petition, but has not participated in the NRC's resolution of the petition or in the development of this proposed rule. Another NRC staff member reviewed the petition prior to its formal submittal to the Commission and participated, to some extent, in the NRC's resolution of the petition and in the development of the proposed rule. The Commission, while aware of this background,

considered the petition on its own merits.

The NRC reviewed the petition and identified the following issues:

A. The petitioners requested that authorized users who are physicians (physician authorized users) be given greater flexibility regarding the medical use of radiopharmaceuticals containing byproduct material. Specifically, the petitioners requested that these physicians be permitted to: (1) Use radiopharmaceuticals to treat diseases that are not listed in the U.S. Food and Drug Administration (FDA) approved package insert; (2) use methods of administration of radiopharmaceuticals for therapy that are not listed in the package insert; (3) use radiopharmaceuticals other than those for which the FDA has accepted an Investigational New Drug (IND) or an approved New Drug Application (NDA); (4) prepare radiopharmaceuticals using radionuclide generators and reagent kits in a manner other than in accordance with the manufacturer's instructions; and (5) compound radiopharmaceuticals in accordance with State law.

B. The petitioners requested that the NRC recognize the practice of nuclear pharmacy by nuclear pharmacists and the certification of nuclear pharmacists by the Board of Pharmaceutical Specialties. Specifically, the petitioners requested that nuclear pharmacists be permitted to: (1) Compound radiopharmaceuticals as described in State or FDA regulations; (2) compound radiopharmaceuticals whose manufacture and distribution are not regulated by the State or FDA; (3) prepare radiopharmaceuticals using radionuclide generators and reagent kits in a manner other than in accordance with the manufacturer's instructions; (4) produce reagent kits; and (5) distribute radiopharmaceuticals that are not regulated by the FDA.

C. Additionally, the petitioners requested that the NRC: (1) Permit categories of research using radioactive drugs that do not require an IND, such as research approved by a Radioactive Drug Research Committee (RDRC); (2) permit the use of radiolabeled biologics for which the FDA has issued a license in response to a product license application (PLA); and (3) clarify its regulations pertaining to specific licenses of broad scope.

In response to the *Federal Register* notice that announced the receipt of the petition, 466 comment letters were received. About 99 percent of the commenters supported and agreed with the petition. After consideration of the public comment letters and consultation with the FDA staff, the Commission

² Next consecutive section number.

determined that some issues should be addressed promptly.

On August 23, 1990 (55 FR 34513), the Commission published an Interim Final Rule to allow, for a period of 3 years, the use of therapeutic radiopharmaceuticals for indications not listed in the package insert and to allow departures from the manufacturer's instructions for preparing diagnostic radiopharmaceuticals using radionuclide generators and reagent kits. In response to the Commission's request for public comments associated with the Interim Final Rule, eight comment letters were received. Seven letters supported the intent of the rule but disagreed with the recordkeeping requirements contained in the rule. One comment letter sought clarification of the rule. The Interim Final Rule permitted specific departures only at the written direction of a physician authorized user, and it does not permit pharmacy-directed departures.

On September 20, 1990, NRC received a "Petition for Reconsideration and for Stay of Action" (Petition for Reconsideration) from Syncor International Corporation (Syncor) regarding NRC's Interim Final Rule. Among other objections, the petition asserted that the rule violates the Atomic Energy Act, the Administrative Procedure Act, and NRC's implementing regulations, and that the recordkeeping requirements of the Interim Final Rule have a direct and negative impact on nuclear pharmacies.

On October 19, 1990, Syncor also filed a "Petition for Review" with the U.S. Court of Appeals for the District of Columbia Circuit (*Syncor International Corp. v. NRC*, NO 90-1495). The petition asked the court to review and set aside portions of the "Interim Final Rule," especially the recordkeeping requirements in 10 CFR 30.34(i)(1)(i-ii).

Also, Syncor requested that the NRC amend its nuclear pharmacy license to permit certain pharmacy-directed departures in addition to the Interim Final Rule's physician-directed departures. Syncor and the NRC staff agreed to hold the court action in abeyance for a period of several months to give the NRC an opportunity to respond to Syncor's request. After considerable interaction among the NRC, Syncor, and the FDA, the requested license amendments for pharmacy-directed departures were granted. Because of the generic interest this licensing action might have had for other commercial nuclear pharmacy licensees, the NRC, on June 26, 1991, sent each of these licensees a letter informing them of the NRC's action in

issuing Syncor's amendments. Until the amendments contemplated in this proposed rulemaking are adopted through the issuance of a final rule, the NRC stands ready to consider similar license amendment requests from other commercial nuclear pharmacies.

Meanwhile, to provide relief from the recordkeeping requirements contained in the Interim Final Rule, the Commission published a final rule entitled "Departure From Manufacturer's Instructions; Elimination of Recordkeeping Requirements" (57 FR 45566; October 2, 1992). This final rule eliminated all the recordkeeping requirements. Based on the information collected under the Interim Final Rule, both the NRC and FDA staff agreed that the major trends in departures that could be identified by the recordkeeping were already discernible. Thus, additional recordkeeping was not necessary.

In a parallel effort, the NRC continued to work on the remaining issues in the ACNP-SNM petition. On August 7, 1991, the NRC conducted a public workshop in Rosemont, Illinois, to present "strawman" language on the training and experience criteria for authorized nuclear pharmacists to representatives of the following organizations: Board of Pharmaceutical Specialties, American Board of Science in Nuclear Medicine, National Association of Boards of Pharmacy, Committee on Radionuclides and Radiopharmaceuticals of the U.S. Council for Energy Awareness, American Pharmaceutical Association, American Society of Hospital Pharmacists, and three graduate schools of pharmacy. Subsequently, the NRC also discussed the proposed resolution of these issues in meetings with the FDA, the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), and the Agreement States. This proposed rulemaking is the evolutionary result of numerous meetings with the aforementioned groups.

The Proposed Modifications

In a policy statement published on February 9, 1979 (44 FR 8242), entitled "Regulation of the Medical Uses of Radioisotopes; Statement of General Policy," the NRC stated:

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.
2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

In conformance with this policy, the Commission proposes to eliminate certain restrictions in the NRC regulations on the practice of medicine and pharmacy (e.g., compounding), and provide the authority for research involving human subjects and the use of radiolabeled biologics. The Commission believes that these restrictions can be eliminated without compromising the level of protection of public health and safety against radiological hazards. The Commission recognizes that physicians have the primary responsibility for the diagnosis and treatment of their patients or human research subjects and recognizes that the nuclear pharmacists have the primary responsibility for the preparation of radioactive drugs. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians and pharmacists will make decisions that are in the best interest of their patients or human research subjects. Furthermore, the pharmacological aspects of radioactive drugs, including drug safety and efficacy, are regulated by the FDA or the States.

The Commission believes that the proposed amendments would provide greater discretion for physician authorized users to use byproduct material in the practice of medicine. Also, the proposed amendments would incorporate into the regulations the concept of an authorized nuclear pharmacist to allow properly qualified pharmacists greater discretion to prepare (including compound) radioactive drugs containing byproduct material for medical use. In response to the petition for rulemaking, the Commission is proposing to:

1. Allow physician authorized users to use therapeutic radioactive drugs containing byproduct material for indications or methods of administration not listed in the FDA-approved package insert;
2. Allow physician authorized users to use radioactive drugs containing byproduct material for research involving human subjects;
3. Allow physician authorized users to use radiolabeled biologics containing byproduct material;
4. Allow medical use licensees and commercial nuclear pharmacies to depart from the manufacturer's instructions for preparing radioactive drugs using radionuclide generators and reagent kits;

5. Allow medical use licensees and commercial nuclear pharmacies to compound radioactive drugs using byproduct material;

6. Delete the existing regulations related to the nonradioactive reagent kits; and

7. Clarify regulatory requirements for specific licenses of broad scope.

Table 1 summarizes the requests made in the petition and the Commission's responses.

In addition to the proposed amendments in response to the issues raised in the petition, the Commission is proposing related or miscellaneous amendments to parts 32 and 35. In general, the objective of these proposed amendments is to clarify, update, and simplify the current regulations. Specifically, these proposed amendments include:

1. In part 32, the Commission is proposing to replace the word "radiopharmaceutical" with the term "radioactive drug" in proposed § 32.72. This change is necessary to include both radiopharmaceuticals and radiolabeled biologics in part 32.

2. In part 35, whenever applicable, the Commission is proposing to use the term "unsealed byproduct material" instead of "radiopharmaceutical" or "radioactive drug." This proposed change is intended to indicate that the Commission's regulations regarding the medical use of byproduct material are focused on radiation safety and are separate from FDA's regulations regarding radioactive drugs. However, to prevent massive changes in part 35, the word "radiopharmaceutical" will continue to be used in existing sections for which no modifications are proposed and for sections in which the only modification is to replace the word "patient" with the term "patient or human research subject." Thus, the word "radiopharmaceutical" will be used as the equivalent of "unsealed

byproduct material" in these sections of the proposed rule.

3. The Commission is proposing to modify the definition of "medical use" in parts 30 and 35 by replacing the term "human beings" with the term "patients or human research subjects" to include the administration of byproduct material to an individual who is participating in a research procedure. In addition, the Commission proposes to delete the language in the definition of "medical use" that the administration of byproduct material be in the practice of medicine in accordance with a license to practice medicine. The definition of other terms in part 35 (e.g., physician) include this licensing concept.

With this proposed definition, applicable requirements in part 35, such as misadministration reporting and quality management program, would also apply to human research subjects; thus, an equivalent level of protection would be provided for both patients and human research subjects.

4. In part 32, the Commission is proposing to clarify the existing regulations regarding the labeling of syringes, vials, generators, or other containers of radioactive drugs. This proposed change is necessary to avoid confusion over the types of information to be submitted.

5. In part 32, the Commission is proposing to replace the text in § 32.72(b) because it is obsolete.

6. In discussing the proposed regulations concerning transfer of radioactive drugs, the Commission has noted later in this preamble that it is sometimes necessary to transfer a dosage of a radioactive drug on a case-by-case basis from one medical use licensee to another medical use licensee. These case-specific transfers would not be considered commercial transfers by the NRC and, therefore, would not require a part 32 license.

7. In part 35, the Commission is proposing to change the lower limit for testing dose calibrators for linearity from 0.37 Megabecquerel (10 microcuries) to 1.1 Megabecquerels (30 microcuries) for consistency with 10 CFR 35.32, "Quality Management Program."

8. In regard to the accuracy, linearity, and geometry tests of dose calibrators, the Commission is proposing to replace the requirement for the Radiation Safety Officer's (RSO) signature with the requirement for the identity of the individual actually performing these tests. This proposed change is necessary to identify the individual who actually performed these tests. Furthermore, this change would provide additional time for the RSO to devote to other radiation safety issues. However, this change would not affect the responsibilities of the RSO that are defined in existing 10 CFR 35.21.

9. The Commission is proposing to update the regulations by recognizing several certification boards in the training and experience requirements.

10. The Commission is proposing that licensees may allow authorized users and authorized nuclear pharmacists who meet certain requirements to use byproduct material without the licensee first obtaining a license amendment from the NRC. Therefore, the Commission is proposing to delete the provisions in part 35 addressing visiting authorized users.

11. The Commission is proposing to modify the requirements for recentness of training of certain authorized users.

12. The Commission is proposing to add requirements regarding the preparation of byproduct material for medical use under the supervision of a physician authorized user and to provide comparable requirements regarding the supervisory responsibilities of authorized nuclear pharmacists.

TABLE 1.—SUMMARY OF REQUESTS IN THE PETITION AND THE COMMISSION'S RESPONSES

Request	Response
Permit authorized users to use radiopharmaceuticals for therapeutic uses not covered in the package insert.	Permit physician authorized users who are qualified for therapeutic administration to use radioactive drugs for therapeutic uses not covered in the package insert.
Permit authorized users to use radioactive drugs for research involving human subjects.	Permit physician authorized users to use radioactive drugs for research, provided that human research subjects are protected.
Permit authorized users to use radiolabeled biologics	Permit physician authorized users to use radiolabeled biologics, provided that dosages of alpha- or beta-emitting radionuclides are measured.
Permit medical use licensees and pharmacies to depart from package inserts when using generators and kits.	Permit physician authorized users and authorized nuclear pharmacists who meet certain training and experience criteria to depart from package inserts when using generators and kits.
Permit medical use licensees and pharmacies to use byproduct material to compound radioactive drugs.	Permit physician authorized users and authorized nuclear pharmacists who meet certain training and experience criteria to prepare (including compound) radioactive drugs.

TABLE 1.—SUMMARY OF REQUESTS IN THE PETITION AND THE COMMISSION'S RESPONSES—Continued

Request	Response
Permit nuclear pharmacists to prepare reagent kits	Delete NRC regulations on reagent kits which do not contain byproduct material. Thus, nuclear pharmacists would be able to prepare reagent kits under applicable law.
Clarify requirements on licenses of broad scope	Clarify the requirements by adding two exemptions in part 35.

13. The responsibilities of the Radiation Safety Committee would be modified to reflect the activities which the proposed changes to part 35 would authorize.

Discussion of Proposed Regulatory Text

Section 30.4. Definitions

The definition of "medical use" would be modified to conform to the corresponding definition proposed for 10 CFR 35.2. This definition would be modified by replacing "patients" with "patients or human research subjects" to include the administration of byproduct material to an individual who is participating in a research procedure.

In addition, the modifications would delete the current statement in this definition that the byproduct material be administered in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. This change would be made because: (1) This aspect of the definition is included in other existing definitions in part 35 (e.g., authorized user and physician); and (2) the definition of "medical use" would include research involving human subjects.

Section 30.34 Terms and Conditions of Licenses

Section 30.34(i) provided interim relief from the restrictions that licensees follow the manufacturer's instructions when preparing radiopharmaceuticals using radionuclide generators and reagent kits. This proposed rulemaking would eliminate these restrictions. Therefore, the Commission proposes to delete § 30.34(i) in its entirety.

Section 32.72 Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Byproduct Material for Medical Use Under 10 CFR Part 35

The Commission proposes to retitle this section to more accurately reflect the operations of licensees (i.e., manufacturers and commercial nuclear pharmacies) regulated under this section.

Section 32.72(a)

This paragraph would be modified to add the word "prepare" and the phrase "transfer for commercial distribution" to more accurately reflect the operations of licensees regulated under this section.

Section 32.72(a)(1)

The proposed amendment to this paragraph is an editorial change to replace "§ 30.33 of this chapter" with "10 CFR 30.33."

Section 32.72(a)(2)

The Commission proposes to modify this paragraph to recognize radioactive drug manufacturers holding registration by the FDA, or appropriate State agencies, as well as commercial nuclear pharmacies licensed by State Boards of Pharmacy (SBPs) and nuclear pharmacies operating in Federal facilities. The intent of this paragraph is to clarify that commercial nuclear pharmacies are covered under this section.

Radioactive drugs transferred from a commercial nuclear pharmacy to another licensee in the normal course of business are considered commercial transfers by the NRC and require a part 32 license. However, the Commission recognizes that in the course of patient care or in the conduct of research procedures, it is sometimes necessary for licensees to transfer a dosage of a radioactive drug on a case-by-case basis from one medical use licensee to another medical use licensee. These case-specific transfers would not be considered commercial transfers by the NRC and, therefore, would not require a Part 32 license.

Section 32.72(a)(3)

The Commission proposes to modify this paragraph to clarify the type of information that should be submitted to the NRC. The words "packaging" and "package" in the existing § 32.72(a)(3) could be interpreted as referring only to the external transportation package (e.g., cardboard box). In the proposed § 32.72(a)(3), the words " * * * per vial, syringe, generator, or other container * * *" would be used to clearly indicate the types of information to be submitted. In addition, the phrase

"group licensees" would be replaced with the phrase "medical use licensees."

Section 32.72(a)(4)

The Commission proposes to modify § 32.72(a)(4)(i) to clarify the types of information that should be contained on the label to be affixed to each container of a radioactive drug. This action is proposed to ensure that the information on the label would include information specified in existing 10 CFR 35.60(b) and 35.61(b).

Also, the Commission proposes to replace the phrase "each package" by the phrase "labels to be applied to containers of radioactive drugs, as specified in 10 CFR 35.60(b) and 35.61(b) * * *" for the same reason as for the proposed changes in § 32.72(a)(3), discussed above.

In addition, the Commission is also proposing to delete the last sentence of § 32.72(a)(4)(i) because it is obsolete.

Furthermore, "time of assay" would be added to the existing "date of assay." This information is necessary for determining the dosage, at the time of administration, for radioactive drugs containing radionuclides with short half-lives.

The Commission also proposes to delete the provision in § 32.72(a)(4)(ii) that required FDA approval before combining labeling information. In addition, the remaining phrase of the existing § 32.72(a)(4)(ii) "the labels, leaflets or brochures required by this paragraph are in addition to the labeling required by the Food and Drug Administration (FDA)" would be replaced by "NRC's labeling requirements are independent of requirements of the U.S. Food and Drug Administration (FDA)." This proposed sentence would be moved to the existing § 32.72(a)(4)(i) which would be renamed § 32.72(a)(4). This proposed amendment would not preclude use of one label if it contains all the required information.

Section 32.72(b)

The Commission proposes to revise this paragraph because the existing text is obsolete.

The Commission proposes new text that would allow an "authorized

nuclear pharmacist" (or individual working under the supervision of the "authorized nuclear pharmacist") working in a commercial nuclear pharmacy to prepare (including compound) radioactive drugs. The NRC is using the phrase "prepare radioactive drugs" in a general sense to include: (1) Using radionuclide generators and nonradioactive reagent kits to produce radioactive drugs; and (2) using byproduct material and other basic ingredients to compound radioactive drugs.

Current regulations require that a part 32 licensee may not depart from manufacturer's instructions when preparing radioactive drugs unless: (1) A license amendment has been granted permitting the departure; or (2) the departure has been requested by a physician authorized user. This requirement restricts the ability of qualified nuclear pharmacists to practice their profession which could otherwise include, but for NRC restrictions, compounding radioactive drugs. The NRC believes that this restriction can be eliminated provided that the pharmacist meets the training and experience requirements in proposed 10 CFR 35.980.

The Commission is proposing to define the terms "medical use" and "authorized nuclear pharmacist" in part 32 by referencing the definition of these terms in proposed 10 CFR 35.2. The definition of "medical use" would be modified to add the term "human research subject" to include the administration of byproduct material to an individual who is participating in a research procedure. It is necessary to define an "authorized nuclear pharmacist" because the proposed amendments would provide pharmacists with the authority to possess and use byproduct material in the practice of nuclear pharmacy.

For purposes of part 32, an authorized nuclear pharmacist also includes those individuals who are currently licensed or registered by a state as a pharmacist and who are also designated, as of the effective date of the final rule, as an "authorized user" on a nuclear pharmacy license issued by the Commission under 10 CFR part 32 to work as an authorized nuclear pharmacist. The Commission believes that this limited "grandfathering" is justified because: (1) currently, these "authorized users" essentially meet the training and experience criteria for an authorized nuclear pharmacist as specified in proposed 10 CFR 35.980(b) (1); and (2) these "authorized users" are currently working in a nuclear pharmacy.

A part 32 "authorized user" who does not currently possess a valid state pharmacy licensure or registration would not be grandfathered as an authorized nuclear pharmacist because, under state law, this individual is not qualified to be a pharmacist. However, such an individual may work in a nuclear pharmacy under the supervision of an authorized nuclear pharmacist.

The Commission proposes to require licensees to submit a copy of the individual's board certification, the license, or the permit, and the state pharmacy licensure or registration to the NRC within 30 days of the date that the licensee permits the individual to work as an authorized nuclear pharmacist. This proposal would reduce the licensees' burden because such a notification would replace the currently required license amendment and the associated amendment fee which are currently necessary before a licensee may allow an authorized nuclear pharmacist to work in its facility. In addition, the proposed action would also eliminate the delay associated with the license amendment process. The NRC will review the notifications upon receipt to verify that the requirements of proposed § 32.72(b) have been met. During the review process, the NRC can consider an individual's character in addition to credentials in determining whether the individual should be approved as an authorized user or authorized nuclear pharmacist, such as verifying that the individual has not committed or caused others to commit any willful violations of the Commission's regulations. At the time of the next licensing action, the names of approved individuals would be listed on the license, without fee, as an authorized nuclear pharmacist.

Section 32.72(c)

The Commission proposes to add this paragraph to explicitly require part 32 licensees to measure and record each dosage of radioactive drugs before transferring these drugs to a medical use licensee. This proposed change is necessary so that the proposed relief to 10 CFR part 35 medical use licensees with respect to measurements can be granted. In proposed § 35.53, medical use licensees would not be required to measure unit dosages of alpha- and beta-emitting radioactive drugs obtained from part 32 licensees before administering these unit dosages to patients or human research subjects. Thus, it is necessary for the part 32 licensees to make these measurements.

Section 32.72(d)

This paragraph is necessary to remind part 32 licensees to comply with applicable FDA, other Federal, and State requirements in addition to applicable NRC requirements. Compliance with NRC requirements does not eliminate the need to comply with other lawful requirements. However, it is not the intent of the Commission to perform inspections to ensure compliance with FDA or State requirements nor to enforce those regulations.

Section 32.73 Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Byproduct Material

The Commission proposes to delete this section in its entirety. Because radionuclide generators would be included as a radioactive drug in proposed § 32.72, it is no longer necessary to include the generators in § 32.73. In addition, the Commission is proposing to discontinue regulating reagent kits because they do not contain byproduct material.

10 CFR Part 35 Medical Use of Byproduct Material

The Commission is proposing to replace the word "patient" with the term "patient or human research subject" as stated in the sections of part 35 which the Commission is proposing to amend. However, only those sections of part 35 which are otherwise being amended are included in the section-by-section "Discussion of Proposed Regulatory Text" which follows. The sections not included in that discussion are: §§ 35.2 (the definitions of *misadministration* and *written directive*), 35.32, 35.33, 35.60, 35.75, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.610, and 35.615. The purpose of using the phrase "patient or human research subject" is to make it explicit that licensees must follow the requirements of part 35 whenever byproduct material or radiation therefrom is being administered either to a patient or to a human research subject. It is necessary to provide an equivalent level of protection for both patients and human research subjects.

Section 35.2 Definitions

Authorized nuclear pharmacist. The Commission proposes to add this new definition. It is necessary to define an authorized nuclear pharmacist because the proposed amendments would provide pharmacists the authority to possess and use byproduct material in the practice of nuclear pharmacy.

independent of the supervision of a physician authorized user.

The definition would specify three groups of individuals that would be qualified as authorized nuclear pharmacists: (1) Individuals certified by the Board of Pharmaceutical Specialties (BPS) as a board certified nuclear pharmacist (BCNP), (2) individuals identified as authorized nuclear pharmacists on a Commission or Agreement State license, or (3) individuals identified as authorized nuclear pharmacists on a permit issued by a Commission or Agreement State specific licensee of broad scope. The individuals in the second and third groups must meet the training and experience requirements specified in the proposed § 35.980(b).

Authorized user. The Commission is proposing to modify the definition of "authorized user" to include those individuals who are: (1) board certified by at least one of the boards listed in paragraph (a) of §§ 35.910, 35.920, 35.930, 35.940, 35.950, or 35.960; (2) identified as an authorized user on a Commission or Agreement State license, or (3) identified as an authorized user on a permit issued by a Commission or Agreement State specific licensee of broad scope. The individuals in the second and third groups must meet the training and experience requirements specified in paragraphs (b) or (c) of §§ 35.910 or 35.920, or paragraph (b) of §§ 35.930, 35.940, 35.950, or 35.960.

Proposed § 35.13 would eliminate, under certain conditions, the requirement for a licensee to submit an amendment to list an authorized user on its license. Instead, proposed § 35.14 would require specific licensees of limited scope to provide a copy of the individual's board certification, the license, or the permit to the Commission within 30 days of the date that the licensee permits the individual to work as an authorized user.

However, before allowing a physician who does not have board certification (or is not listed on a license or a permit) to work as an authorized user, the specific licensee of limited scope must continue to submit a license amendment and obtain NRC approval. The NRC will review the notifications upon receipt to verify that the requirements of proposed § 32.72(b) have been met. During the review process, the NRC may consider character in addition to credentials in determining whether the individual should be approved as an authorized user or authorized nuclear pharmacist, such as to verify that the individual has not committed or caused others to commit any willful violations of the Commission's regulations.

Medical use. The Commission is proposing to modify the definition of "medical use" by replacing the term "human beings" with the term "patients or human research subjects" to include the administration of byproduct material to an individual who is participating in a research procedure.

Currently, the NRC allows by license condition specific medical use licensees of broad scope to perform research involving human subjects using byproduct material. Because part 35 is silent on research involving human subjects using byproduct material, part 35 specific medical use licensees of limited scope may only conduct such research if the NRC grants a license amendment to do so. The effects of the current regulatory framework are to inhibit or delay research activities by specific medical use licensees of limited scope.

Medical research involving human subjects not using radioactive material is currently conducted by large medical institutions and community hospitals through, for example, their participation in regional and national research programs. Such research may lead to a better understanding of diseases, improved diagnostic and therapeutic methods, new or better drug products or medical devices, or essential basic scientific information.

Current regulations require all medical institutions to have a Radiation Safety Committee whose responsibilities include oversight of all uses of licensed material. Other part 35 licensees are required to have a Radiation Safety Officer who has such responsibility. The Commission believes that restrictions on research can be reduced provided there are certain additional protections of human subjects as described in proposed § 35.6.

The proposed provisions include requiring a licensee who conducts research involving human subjects to: (a) Possess a part 35 license authorizing medical use, (b) implement the Federal Policy for the Protection of Human Subjects or comply with specific NRC licensing requirements, and (c) have a physician authorized user who will supervise the administration of the byproduct material.

The Commission believes that information gathered through research, although it may not benefit the individual subject of the research, has the potential to benefit the society at large. Therefore, given adequate protection of the rights and radiological safety of human research subjects, it is appropriate to permit this activity.

Furthermore, under the proposed definition of "medical use," the

applicable provisions of part 35, such as requirements related to misadministrations and the quality management program, also apply to a human research subject. Thus, an equivalent level of protection would be provided for both patients and human research subjects.

The Commission is also proposing to delete the current statement in this definition that the byproduct material be administered in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. This change is being made because this aspect of the definition is included in other existing definitions in part 35 (e.g., authorized user and physician).

Pharmacist. The Commission is proposing to add this new term to define a pharmacist in part 35 to complement another new definition "authorized nuclear pharmacist."

Section 35.6 Provisions for Research Involving Human Subjects

The Commission is proposing to add this section to address the protection of the rights of human subjects who would be involved in research using byproduct material. The Commission believes that most research involving human subjects using byproduct material is currently conducted, funded, supported, or regulated by another federal agency which has implemented the Federal Policy for the Protection of Human Subjects¹ (56 FR 28002; June 18, 1991). Therefore, the rights of human subjects involved in such research activities would be protected by the other federal agency funding the research under the provisions of the Federal Policy. The Federal Policy has been implemented by 15 Federal departments or agencies (not including NRC) and includes provisions, among others, for obtaining Institutional Review Board (IRB) review and approval of the research activities and informed consent from the human subjects. The NRC understands that compliance with the Federal Policy by institutions conducting research involving human subjects is achieved through the use of letters of assurance of compliance and certain reporting requirements.

This section proposes to allow the licensees covered by the Federal Policy as adopted by another Federal agency to conduct human research without prior NRC approval. If a licensee's activities

¹ For a copy of the Federal Policy for the Protection of Human Subjects contact: Office for Protection from Research Risks, National Institute of Health, Building 31, room 5B59, Bethesda, MD 20892, telephone (301) 496-7005.

are not funded by another Federal agency which has adopted the Federal Policy, the licensee would need to apply for and obtain approval of a specific amendment to its NRC license prior to conducting research involving human subjects using byproduct material. During the review of the license amendment application, the NRC would ensure that the proposed research would receive approval of the IRB and obtain the human subject's informed consent. The Commission is soliciting public comment on the number and type of research activities which would not be funded by another Federal agency which has adopted the Federal Policy and, thus under the proposed rule, would require a license amendment.

The focus of NRC inspections would be to confirm that both types of licensees have obtained prior IRB review and approval of the research activities and informed consent of the human subjects.

The Commission is soliciting public comment on whether it should broaden or narrow its focus to require compliance with all or none of the provisions of the Federal Policy or equivalent license conditions. In making comments, consideration should be given to the fact that all the radiation safety provisions of 10 CFR part 35 are proposed to be made applicable to research involving human subjects.

Section 35.7 FDA, Other Federal, and State Requirements

This section is necessary to remind medical use licensees to comply with applicable FDA, other Federal, and State requirements. However, it is not the intent of the Commission to perform inspections to ensure compliance with FDA or State requirements nor to enforce those regulations.

Section 35.11 License Required

The Commission is proposing to add paragraph (c), in parallel with the existing paragraph (b), to this section. The new paragraph (c) would permit an individual to prepare unsealed byproduct material for medical use under the supervision of an authorized nuclear pharmacist or authorized user who is a physician. Also, the existing paragraph (a) would be revised by replacing the phrase "paragraph (b)" with "paragraphs (b) or (c)."

**Section 35.12 Application for License, Amendment, or Renewal*

The Commission is proposing to add paragraph (e) to this section. This paragraph would remind part 35 medical use licensees that they may

apply for a Type A specific license of broad scope under 10 CFR part 33.

Section 35.13 License Amendments

The Commission proposes to modify paragraph (b) of this section to delete the term "visiting authorized user." Instead, under the proposed provisions, the licensees could allow, without a license amendment, an individual to work as an authorized user provided that the individual is: (1) Certified by a board listed in subpart J, (2) identified as an authorized user on a Commission or Agreement State license, or (3) identified as an authorized user on a permit issued by a Commission or Agreement State specific licensee of broad scope. However, the licensee would be required to provide a copy of an individual's board certification, the license, or the permit to the Commission within 30 days of the date that the licensee permits the individual to work as an authorized user (See proposed § 35.14).

The Commission also proposes to add an exception for authorized nuclear pharmacists to this section like the exception for authorized users.

Section 35.14 Notification

In addition to the existing notification requirement, the Commission proposes to amend this section to require specific licensees of limited scope to submit a copy of an individual's board certification, the license, or the permit as discussed in § 35.13. This proposal would reduce licensees' burden because this notification would replace the currently required license amendment and the associated amendment fee which are currently necessary before a specific licensee of limited scope may allow an authorized user to work in its facility. In addition, the proposed action would also eliminate the delay associated with the license amendment process. The NRC will review the notifications upon receipt to verify that the requirements of this section have been met. In addition, the NRC would verify at that time that this individual has not committed or caused another individual to commit any willful violations of the Commission's regulations. At the time of the next licensing action, the name of this individual would be listed on the license, without fee, as an authorized user. The Commission also proposes to apply this section to authorized nuclear pharmacists in the same manner as for authorized users.

Section 35.15 Exemptions Regarding Type A Specific Licenses of Broad Scope

The Commission is proposing to clarify requirements on Type A specific licenses of broad scope by adding the proposed exemptions. This proposed section would specify that an application for and receipt of a license amendment would not be necessary for the following actions: (1) Permit a new authorized user or authorized nuclear pharmacist to work under the license; and (2) permit a change of the area of use of byproduct material within the address identified in the license. Also, specific licensees of broad scope would be exempt from certain notification requirements specified in proposed § 35.14.

These changes are being made to ensure that the proposed rule conforms with the current practice regarding Type A specific licensees of broad scope. Under current practice, the other prescriptive and performance requirements of Part 35 apply to Type A specific licensees of broad scope. Because a Part 33 specific licensee of broad scope is required to establish more complete administrative procedures and controls to ensure radiation safety than a Part 35 licensee, the exemptions would not reduce protection of public health and safety.

Section 35.22 Radiation Safety Committee

The Commission is proposing to amend paragraph (b)(2) to apply this section to authorized nuclear pharmacists in the same manner as for authorized users.

The Commission also proposes to require the Radiation Safety Committee to review an individual's certification, license, or permit, and determine, based on the proposed § 35.13(b)(1) through (b)(4), whether to allow the individual to work as an authorized user or authorized nuclear pharmacist without submitting a license amendment for NRC approval.

Section 35.25 Supervision

Existing paragraph (b) would be redesignated as paragraph (c).

The Commission is proposing to add a new paragraph (b) to address the supervisory responsibilities of the licensee, the authorized nuclear pharmacist, and the physician authorized user who prepare unsealed byproduct material for medical use. Specifically, under the proposed paragraph, an authorized nuclear pharmacist or a physician authorized user would be able to permit

individuals to prepare unsealed byproduct material for medical use, provided that the individuals are adequately supervised. This section describes the level of supervision that an authorized nuclear pharmacist or a physician authorized user would be required to provide to individuals who are preparing unsealed byproduct material for medical use under their supervision.

Section 35.27 Visiting Authorized User

The Commission is proposing to delete this section which permits a visiting authorized user to work for a period of 60 days each year without a license amendment. Under proposed § 35.13(b), the concept of a visiting authorized user would no longer be necessary. Any individual who meets § 35.13(b)(1) through (b)(4) would be permitted to work in a licensee's facility either temporarily or permanently. However, under proposed § 35.14, the licensee would be required to provide a copy of the individual's board certification, the license, or the permit to the NRC.

Section 35.49 Supplier for Sealed Sources or Devices for Medical Use

The Commission is proposing to modify this section as follows:

The title of this section would be modified to indicate that this section would only apply to sealed sources or devices for medical use.

The Commission is proposing to delete the reference to §§ 32.72 and 32.73 in the proposed § 35.49(a) because, under the proposed rule, the requirements applicable to unsealed byproduct material for medical use would be incorporated into the proposed §§ 35.100, 35.200, and 35.300. Furthermore, the proposed rule would allow medical use licensees to prepare (including compound) radioactive drugs. Therefore, limiting suppliers of radioactive drugs to manufacturers or commercial nuclear pharmacies would no longer be necessary. However, the requirements applicable to sealed sources or devices as specified in § 32.74 would remain in the proposed § 35.49(a).

In addition, the Commission is proposing to delete existing § 35.49(b). Under the proposed rule, all the requirements applicable to reagent kits would be deleted because the reagent kits do not contain byproduct material. Therefore, this paragraph would no longer be necessary. The existing § 35.49(c) would be redesignated as § 35.49(b).

Section 35.50 Possession, Use, Calibration, and Checks of Dose Calibrators

The Commission is proposing the following modifications to this section.

(1) In paragraph (a), the phrase "photon-emitting" would be inserted to clarify that this section is applicable only to photon-emitting radionuclides. This modification would avoid confusion between this section and proposed § 35.52 pertaining to instruments to measure dosages of alpha- or beta-emitting radionuclides.

(2) The Commission is proposing to use the term "radionuclides" instead of the term "radiopharmaceuticals." The new term is broader and would include radiolabeled biologics as well as radiopharmaceuticals.

(3) In paragraph (b)(3) regarding the linearity test of the dose calibrator, the lower limit for the test would be changed from 0.37 megabecquerel (10 microcuries) to 1.1 megabecquerel (30 microcuries). This modification is necessary for consistency with the requirements of the Quality Management Program (§ 35.32) and proposed § 35.53(c)(3).

(4) In paragraphs (e)(2) through (e)(4) regarding records on the accuracy, linearity, and geometry tests of dose calibrators, the Commission is proposing to require the identity of the individual actually performing these tests rather than the Radiation Safety Officer's (RSO) signature. This proposed change is necessary to identify the individual who actually performed these tests. Furthermore, this change would provide additional time for the RSO to devote to other radiation safety issues.

Section 35.52 Possession, Use, Calibration, and Checks of Instrumentation to Measure Dosages of Alpha- and Beta-Emitting Radionuclides

The Commission is proposing to require medical use licensees to possess and use instrumentation to measure alpha- or beta-emitting radionuclides. New radiolabeled biologics are being developed which have potential benefits for diagnosis and treatment in medicine. Some of these biologics may contain alpha- or beta-emitting radionuclides that do not emit photons of sufficient energy or frequency to be detected or quantified in a dose calibrator. Thus, this section is proposed so that medical use licensees would be able to determine that the correct dosages will be administered to patients or human research subjects.

The measurement requirements of this section would not apply to unit

dosages obtained from a manufacturer or a commercial nuclear pharmacy for the following reasons: (1) The instrumentation for measuring activity of alpha- or beta-emitters is expensive and not commonly available in a medical use licensee's facility; (2) the frequency of using alpha- or beta-emitters for most medical use licensees is very low; and (3) the manufacturer or the commercial nuclear pharmacy would be required, pursuant to proposed § 32.72(c), to measure each dosage of a radioactive drug prior to transfer for commercial distribution.

Section 35.53 Measurement of Dosages of Unsealed Byproduct Material for Medical Use

The Commission is proposing to modify this section as follows:

(1) In the title, the term "radiopharmaceutical dosages" would be replaced by the phrase "dosages of unsealed byproduct material for medical use." This is proposed to avoid the connotation that the Commission is regulating drug safety and efficacy. The word "unsealed" is proposed to emphasize that this section applies only to unsealed byproduct material for medical use. This section does not apply to sealed sources such as teletherapy or brachytherapy sources.

(2) Existing paragraphs (a) and (b) have been combined as proposed paragraph (a). However, the measurement requirements are the same.

(3) The new text of paragraph (b) would require medical use licensees to measure dosages of alpha- or beta-emitting radionuclides, except for unit dosages obtained from a manufacturer or a commercial nuclear pharmacy. Medical use licensees would be required to measure dosages that will be administered to patients or human research subjects.

The measurement requirements of this section would not apply to unit dosages of alpha- or beta-emitting radionuclides because the manufacturer or the commercial nuclear pharmacy must measure the dosage before distributing it to a medical use licensee. Also, the proposed rule would allow a licensee to use the combination of several measurements and calculations to determine the dosage because it may not be possible to measure alpha- or beta-emitting radionuclides by a single measurement.

(4) In paragraph (c)(3), 0.37 megabecquerel (10 microcuries) would be changed to 1.1 megabecquerels (30 microcuries). This modification is necessary for consistency with the requirements of the Quality

Management Program (§ 35.32). Also, because the radiological risk associated with a dosage of 1.1 megabecquerels (30 microcuries) is small, it is unnecessary to require more than just recording that the dosage is less than 1.1 megabecquerels (30 microcuries).

Section 35.100 Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion

The current § 35.100 requires medical use licensees to use only byproduct material in a radiopharmaceutical for uptake, dilution and excretion for which the FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a New Drug Application (NDA). The effect of this restriction is to prohibit a licensee from using other types of radioactive drugs such as those approved by a Radioactive Drug Research Committee (RDRC), unless a license amendment is received authorizing their use.

The Commission believes that these restrictions can be eased without compromising the level of protection of public health and safety against radiological hazards because of certain conditions which must be met (discussed below). In addition, the Commission recognizes that physicians have the primary responsibility for the diagnosis and treatment of their patients or human research subjects. Commission regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interest of their patients or human research subjects. Furthermore, the pharmacological aspects of radioactive drugs, including drug safety and efficacy, are regulated by the FDA.

Detailed discussions of proposed changes are presented below.

The Commission is proposing to use the term "unsealed byproduct material" instead of the term "radiopharmaceutical" in this proposed section. This is proposed to avoid the connotation that the Commission is regulating drug safety and efficacy. The word "unsealed" is proposed to emphasize that this section applies only to unsealed byproduct material for medical use and does not apply to sealed sources such as teletherapy or brachytherapy sources.

This proposed modification would provide medical use licensees with the maximum flexibility to use any byproduct material for medical use provided that the material is: (1) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72; or (2) prepared by an authorized nuclear pharmacist, a physician

authorized user who meets the training requirements specified in § 35.920, or an individual under supervision of either, as specified in proposed § 35.25.

In addition, the Commission is proposing to modify this section as follows:

(1) The phrase "unsealed byproduct material prepared for medical use" would be used. This phrase includes "IND" and "NDA," as specified in the existing § 35.100, and other radioactive drugs containing byproduct material that are not specified in the existing § 35.100.

(2) The supplier or preparer of unsealed byproduct material for medical use would be specified under this section. A licensee may obtain byproduct material from a manufacturer or a commercial nuclear pharmacy.

(3) This proposed section would allow licensees to use unsealed byproduct material to prepare (including compound) radioactive drugs by physician authorized users who meet § 35.920, authorized nuclear pharmacists, or individuals under their supervision. The NRC is using the phrase "prepare radioactive drugs" in a general sense to include: (a) using radionuclide generators and nonradioactive reagent kits to produce radioactive drugs and (b) using byproduct material and other basic ingredients to compound radioactive drugs.

(4) This proposed section would require a physician authorized user who wants to prepare radioactive drugs to meet the requirements specified in existing § 35.920. Training and experience requirements specified in existing §§ 35.910 and 35.930, although adequate to administer byproduct material, would not be sufficient for preparing radioactive drugs. Similar training and experience requirements for authorized nuclear pharmacists are proposed in § 35.980.

(5) This proposed section would also allow an individual under the supervision of a physician authorized user or an authorized nuclear pharmacist to use byproduct material to prepare (including compound) radioactive drugs. A part 35 medical use licensee operating a nuclear pharmacy to prepare radioactive drugs for use within the licensee's facility would not be required to obtain a part 32 license, unless the nuclear pharmacy transfers radioactive drugs for commercial distribution. The proposed rule language in § 35.25 would require the supervising physician authorized user or authorized nuclear pharmacist to instruct the individual on radiation safety principles and procedures and

would require the individual to follow the procedures.

(6) The Commission recognizes that, in the course of patient care or in the conduct of research procedures, it is sometimes necessary to transfer a dosage of a radioactive drug, on a case-by-case basis, from one medical use licensee to another medical use licensee. These case-specific transfers would not be considered commercial transfers by the NRC and, therefore, would not require a part 32 license. Licensees should be aware that other than infrequent transfers may require a license for commercial transfer of byproduct material.

Section 35.200 Use of Unsealed Byproduct Material for Imaging and Localization Studies

Paragraph (a) of the current § 35.200 restricts medical use licensees to use byproduct material in a radiopharmaceutical for which the FDA has accepted an IND or approved an NDA. The effect of this restriction is to prohibit a licensee from using other types of radioactive drugs such as those approved by a Radioactive Drug Research Committee (RDRC), unless a license amendment is received that authorizes such use. Furthermore, paragraphs (b) and (c) of the current section require licensees to follow the manufacturer's instructions for eluting radionuclide generators and preparing reagent kits unless a departure is directed by a physician authorized user.

The Commission believes that these restrictions can be eased without compromising the level of protection of public health and safety against radiological hazards because of certain conditions which must be met (discussed below). In addition, the Commission recognizes that physicians have the primary responsibility for the diagnosis and treatment of their patients or human research subjects and recognizes that the nuclear pharmacists have the primary responsibility for the preparation of radioactive drugs. Commission regulations are predicated on the assumption that properly trained and adequately informed physicians and pharmacists will make decisions that are in the best interest of their patients or human research subjects. Furthermore, the pharmacological aspects of radioactive drugs, including drug safety and efficacy, are regulated by the FDA.

Detailed discussions of proposed changes are presented below.

(1) The Commission is proposing to use the term "unsealed byproduct material" instead of the term "radiopharmaceutical" in this proposed

section to avoid the connotation that the Commission is regulating drug safety and efficacy. Also, this phrase includes "IND" and "NDA," as specified in the existing § 35.200, and other radioactive drugs containing byproduct material that are not specified in the existing § 35.200.

(2) This proposed modification would provide medical use licensees with the maximum flexibility to use any byproduct material for medical use provided that the material is: (a) obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or (b) prepared by an authorized nuclear pharmacist, a physician authorized user who meets the training requirements specified in § 35.920, or an individual under supervision of either, as specified in proposed § 35.25.

(3) The supplier or preparer of unsealed byproduct material for medical use would be specified under this section. A licensee may obtain byproduct material from a manufacturer or a commercial nuclear pharmacy.

(4) This proposed section would allow licensees to use unsealed byproduct material to prepare (including compound) radioactive drugs by physician authorized users who meet § 35.920, authorized nuclear pharmacists, or individuals under their supervision. The NRC is using the phrase "prepare radioactive drugs" in a general sense to include: (a) using radionuclide generators and nonradioactive reagent kits to produce radioactive drugs; and (b) using byproduct material and other basic ingredients to compound radioactive drugs.

(5) This proposed section would also allow an individual under the supervision of a physician authorized user or an authorized nuclear pharmacist to use byproduct material to prepare (including compound) radioactive drugs. The proposed rule language in § 35.25 would require the supervising physician authorized user or authorized nuclear pharmacist to instruct the individual on radiation safety principles and procedures and would require the individual to follow the procedures.

(6) The Commission recognizes that, in the course of patient care or in the conduct of research procedures, it is sometimes necessary to transfer a dosage of a radioactive drug, on a case-by-case basis, from one medical use licensee to another medical use licensee. These case-specific transfers would not be considered commercial transfers by the NRC and, therefore, would not require a part 32 license.

Section 35.300 Use of Unsealed Byproduct Material for Therapeutic Administration

Paragraph (a) of the current § 35.300 restricts medical use licensees to use byproduct material in a radiopharmaceutical for which the FDA has accepted an IND or approved an NDA. Also, this paragraph requires licensees to comply with the package insert instructions regarding indications and method of administration unless a departure is directed by a physician authorized user.

While recognizing that therapeutic dosages result in greater radiation exposure, the Commission believes that these restrictions can be eased without compromising the level of protection of public health and safety against radiological hazards because of certain conditions which must be met (discussed below). In addition, the Commission recognizes that physicians have the primary responsibility for the diagnosis and treatment of their patients or human research subjects. Commission regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interest of their patients or human research subjects. Furthermore, the pharmacological aspects of radioactive drugs, including drug safety and efficacy, are regulated by the FDA.

Detailed discussions of proposed changes are presented below.

(1) The Commission is proposing to use the term "unsealed byproduct material" instead of the term "radiopharmaceutical" in this proposed section to avoid the connotation that the Commission is regulating drug safety and efficacy. Also, this phrase includes "IND" and "NDA," as specified in the existing § 35.300, and other radioactive drugs containing byproduct material that are not specified in the existing § 35.300.

(2) This proposed modification would provide medical use licensees with the maximum flexibility to use any byproduct material for medical use provided that the material is: (a) obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or (b) prepared by an authorized nuclear pharmacist, a physician authorized user who meets the training requirements specified in § 35.920, or an individual under supervision of either, as specified in proposed § 35.25.

(3) The supplier or preparer of unsealed byproduct material for medical use would be specified under this section. A licensee may obtain

byproduct material from a manufacturer or a commercial nuclear pharmacy.

(4) This proposed section would allow licensees to use unsealed byproduct material to prepare (including compound) radioactive drugs by physician authorized users who meet § 35.920, authorized nuclear pharmacists, or individuals under their supervision.

(5) This proposed section would also allow an individual under the supervision of a physician authorized user or an authorized nuclear pharmacist to use byproduct material to prepare (including compound) radioactive drugs. The proposed rule language in § 35.25 would require the supervising physician authorized user or authorized nuclear pharmacist to instruct the individual on radiation safety principles and procedures and would require the individual to follow the procedures.

(6) The Commission recognizes that, in the course of patient care or in the conduct of research procedures, it is sometimes necessary to transfer a dosage of a radioactive drug, on a case-by-case basis, from one medical use licensee to another medical use licensee. These case-specific transfers would not be considered commercial transfers by the NRC and, therefore, would not require a part 32 license.

Section 35.900 Radiation Safety Officer

The Commission is proposing to modify this section to recognize the certification in nuclear medicine by the Royal College of Physicians and Surgeons of Canada and in radiation oncology physics by the American Board of Medical Physics.

Section 35.910 Training for Uptake, Dilution, and Excretion Studies

The Commission is proposing, as recommended by the ACMUI, to modify this section to recognize the certification in nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

Section 35.920 Training for Imaging and Localization Studies

The Commission is proposing, as recommended by the ACMUI, to modify this section to recognize the certification in nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

Section 35.930 Training for Therapeutic Use of Unsealed Byproduct Material

The Commission is proposing to amend § 35.930(a)(2) to recognize the

certification in radiation oncology by the American Board of Radiology (ABR). In 1987, the ABR renamed "therapeutic radiology" as "radiation oncology" but the criteria for certification remain the same. Therefore, it is necessary to recognize both certifications.

Section 35.940 Training for Use of Brachytherapy Sources

The Commission is proposing to amend § 35.940(a)(1) to recognize the certification in radiation oncology by the American Board of Radiology (ABR).

Section 35.950 Training for Use of Sealed Sources for Diagnosis

The Commission is proposing to amend § 35.950(a)(1) to recognize the certification in radiation oncology by the American Board of Radiology (ABR) and the certification in nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

Section 35.960 Training for Teletherapy

The Commission is proposing to amend § 35.960(a)(1) to recognize the certification in radiation oncology by the American Board of Radiology (ABR).

Section 35.961 Training for Teletherapy Physicist

The Commission is proposing to modify this section to recognize the certification in radiation oncology physics by the American Board of Medical Physics.

Section 35.972 Recentness of Training

Existing § 35.972 required that an individual's training must have been acquired within the last 5 years. The Board of Pharmaceutical Specialties (BPS) recertifies board certified nuclear pharmacists (BCNP) every 7 years. Based on BPS's 11 years experience with recertification, the Commission is proposing to replace 5 years with 7 years. This action is necessary to achieve consistency for recentness of training requirements among authorized users, Radiation Safety Officers, teletherapy physicists, and authorized nuclear pharmacists. The Commission is requesting public comment on which period (either 5 or 7 years) is more appropriate and the basis for any recommendation.

Section 35.980 Training for Authorized Nuclear Pharmacist

The Commission is proposing to add a new section that would contain specific training requirements for an authorized nuclear pharmacist. This action is necessary because an authorized nuclear pharmacist may be

responsible for handling, preparing, and distributing radioactive drugs to multiple medical institutions. Thus, authorized nuclear pharmacists potentially impact the radiological safety of patients or human research subjects at many medical institutions. The effect of these training requirements will provide sufficient assurance that individuals satisfying these training criteria will safely prepare and distribute radioactive drugs.

In this section, the Commission is proposing two methods for an individual to qualify as an authorized nuclear pharmacist:

(1) In paragraph (a), the Commission is proposing to recognize certification by the Board of Pharmaceutical Specialties as a nuclear pharmacist as satisfying the training requirements.

(2) In paragraph (b), in lieu of board certification, an alternative method to qualify for an authorized nuclear pharmacist is proposed. A candidate would be required to: (i) Complete 700 hours in a structured educational program consisting of both didactic training and supervised experience in a nuclear pharmacy, and (ii) obtain a written certification from a preceptor that the candidate has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Implementation Plan and Agreement State Compatibility

The effective date of this amendment would be 6 months after the publication of the final amendment in the Federal Register.

On July 15 and 16, 1992, the NRC held a workshop with representatives of 23 Agreement States to discuss the draft rule language for the proposed rulemaking. The Agreement State participants expressed a clear consensus that this proposed rulemaking be either not an item of compatibility or the lowest level of compatibility possible.

However, because this amendment has safety significance for Agreement State licensees as well as NRC licensees, this proposed amendment would be an item of compatibility for the Agreement States. All definitions contained in §§ 30.4 and 35.2 would be Division 1 items of compatibility. The definitions contained in this rulemaking must be the same for all NRC and Agreement State licensees so that consistency will be maintained.

Additionally, the Commission believes that §§ 32.72, 35.6, 35.22(b)(2), 35.25, 35.50, 35.52, 35.53, 35.920, 35.972 and 35.980 should be Division 2 items of compatibility, because these requirements are necessary to ensure

adequate protection of the public health and safety. For example, §§ 35.920 and 35.980 provide the radiation safety training and experience criteria for authorized users and authorized nuclear pharmacists that are important prerequisites for ensuring that byproduct material is handled safely. It should be noted that changing § 35.920 to a Division 2 item of compatibility would impact those authorized users who want to compound radioactive drugs as well as those authorized users who only want to perform imaging procedures currently allowed under § 35.200. The Agreement States would be allowed to establish requirements that are more stringent than NRC's requirements, but not less stringent.

It would be appropriate for Agreement States to adopt the remaining sections of part 35 in this proposed rulemaking, but it is not necessary to require any degree of uniformity between NRC and the States. Therefore, a Division 3 item of compatibility would be appropriate for such sections.

The Commission is currently reevaluating its practices concerning the implementation of the provision in the Atomic Energy Act which provides that the Agreement States' regulatory programs are to be compatible with NRC's. This reevaluation will include early and significant involvement of the Agreement States. At the conclusion of this effort, the Commission will implement generic guidance on the application of compatibility.

For comparison, the existing compatibility levels are as follows: definitions in § 30.4 are Division 1 items of compatibility; § 32.72 is a Division 2 item of compatibility; the definitions associated with the quality management rule and misadministrations in § 35.2 are Division 1 items of compatibility; §§ 35.32 and 35.33 are Division 2 items of compatibility; § 35.8 is a Division 4 item of compatibility; and all other sections of part 35 are Division 3 items of compatibility.

The NRC expects Agreement States to adopt rules required to maintain compatibility within three years after NRC's rules become effective. Some Agreement States, faced with administrative and resource constraints, may find the three year goal difficult to attain and may prefer that NRC extend flexibility in such cases to allow the States to implement the requirements through license conditions. The NRC requests public comment on permitting Agreement States flexibility in this regard, and if permitted, under what conditions.

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that the proposed amendments, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required. The proposed amendments would provide greater flexibility for physician authorized users to use byproduct material in the practice of medicine. The proposed amendments would also incorporate into the regulations the concept of authorized nuclear pharmacists to permit properly qualified pharmacists to prepare radioactive drugs containing byproduct material in the practice of pharmacy.

The proposed amendments would allow physician authorized users greater discretion to prepare and use radioactive drugs containing byproduct material. The proposed amendments would also allow authorized nuclear pharmacists greater discretion to prepare radioactive drugs containing byproduct material. It is expected that there will be no increase in radiation exposure to the public or to the environment beyond the exposures currently resulting from delivering the byproduct material or radiation from byproduct material to patients or human research subjects. The draft environmental assessment and finding of no significant impact on which this determination is based is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the draft environmental assessment and the finding of no significant impact are available from Samuel Z. Jones or Anthony N. Tse (see **FOR FURTHER INFORMATION CONTACT** heading).

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

The reduction in public burden for this collection of information is estimated to be a savings of 420 hours per year for 300 NRC licensees, or an average 1.4 hours per year per licensee, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the

data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB-7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-3019 (3150-0001, -0010, and -0120), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the benefits and impacts considered by the Commission. The draft regulatory analysis is available for inspection at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the draft analysis are available from Samuel Z. Jones or Anthony N. Tse (see **FOR FURTHER INFORMATION CONTACT** heading).

The Commission requests public comments on the draft regulatory analysis. Comments on the draft regulatory analysis may be submitted to the NRC as indicated under the **ADDRESSES** heading.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that, if adopted, this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect medical use licensees including some private practice physicians. Some of these licensees would be considered small entities under the NRC's size standards (56 FR 56672; November 6, 1991). The proposed amendments would provide greater discretion for physician authorized users to use byproduct material in the practice of medicine. The proposed amendments would also incorporate into the regulations the concept of authorized nuclear pharmacists to allow properly qualified pharmacists greater discretion to prepare (including compound) radioactive drugs containing byproduct material for medical use. This rulemaking, if adopted, would reduce regulatory burdens on medical use licensees, including small entities.

Any small entity subject to this regulation who determines that, because of its size, it is likely to bear a disproportionate adverse economic

impact should notify the Commission by a letter that indicates the following:

(a) The licensee's size and how the proposed regulation would result in a significant economic burden or whether the resources necessary to implement this amendment could be more effectively used in other ways to optimize the safety of patients or human research subjects, as compared to the economic burden on a larger licensee;

(b) How the proposed regulation could be modified to take into account the licensee's differing needs or capabilities;

(c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation were modified as suggested by the licensee;

(d) How the proposed regulation, as modified, could more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individual or group;

(e) How the proposed regulation, as modified, would still adequately protect the public health and safety.

Backfit Analysis

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

List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalty, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 32

Byproduct material, Labeling, Nuclear materials, Criminal penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Criminal penalty, Drugs, Health facilities, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the

Commission is proposing to adopt the following amendments to 10 CFR parts 30, 32, and 35.

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

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

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. In § 30.4, the definition of *medical use* is revised to read as follows:

§ 30.4 Definitions.

* * * * *

Medical use means the intentional internal or external administration of byproduct material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

* * * * *

3. In § 30.8, paragraphs (b) and (c) are revised to read as follows:

§ 30.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 30.9, 30.11, 30.15, 30.19, 30.20, 30.32, 30.34, 30.35, 30.36, 30.37, 30.38, 30.41, 30.50, 30.51, 30.55, and Appendix A.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §§ 30.32, 30.37, and 30.38, NRC Form 313 is approved under control number 3150-0120.

(2) In § 30.36, NRC Form 314 is approved under control number 3150-0028.

§ 30.34 [Amended]

4. Section 30.34 is amended by removing paragraph (i).

PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

5. The authority citation for part 32 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

6. In § 32.8, paragraphs (b) and (c) are revised to read as follows:

§ 32.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 32.12, 32.14, 32.15, 32.16, 32.17, 32.18, 32.19, 32.20, 32.22, 32.25, 32.26, 32.29, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.56, 32.57, 32.58, 32.61, 32.70, 32.71, 32.72, and 32.74.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 32.11, NRC Form 313 is approved under control number 3150-0120.

(2) [Reserved]

7. Section 32.72 is revised to read as follows:

§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized pursuant to part 35 of this chapter will be approved if:

(1) The applicant satisfies the general requirements specified in 10 CFR 30.33;

(2) The applicant submits evidence that the applicant is at least one of the following:

- (i) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;
- (ii) Registered or licensed with a state agency as a drug manufacturer;
- (iii) Licensed as a pharmacy by a State Board of Pharmacy; or
- (iv) Operating as a nuclear pharmacy within a Federal medical institution.

(3) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and

the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(4) A label is affixed to each container of a radioactive drug to be transferred for commercial distribution. The label must include the name of the radioactive drug or its abbreviation, quantity of radioactivity, and date and time of assay. In addition, the label for the syringe or syringe radiation shield must also contain the clinical procedure to be performed or the patient's or the human research subject's name. Furthermore, the label, or the leaflet or brochure that accompanies the radioactive drug must contain a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the byproduct material to persons licensed to use byproduct material pursuant to 10 CFR 35.100, 35.200, or 35.300, as appropriate, and to persons who hold an equivalent license issued by an Agreement State. The label, or the leaflet or brochure must also note that other regulatory approvals may be required. NRC's labeling requirements are independent of requirements of the U.S. Food and Drug Administration (FDA).

(b) (1) A licensee described by paragraph (a)(2)(iii) or (iv) of this section may prepare radioactive drugs for medical use, as defined in 10 CFR 35.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as defined in 10 CFR 35.2, or an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR 35.25.

(2) In addition, for purposes of this section, an *authorized nuclear pharmacist* is a pharmacist who is currently licensed or registered by a state to practice pharmacy and designated, as of the effective date of the final rule, as an "authorized user" on a nuclear pharmacy license issued by the Commission under this part.

(3) A licensee shall provide to the Commission a copy of the individual's board certification, the license, or the permit, and the state pharmacy licensure or registration, respectively, for each individual within 30 days of the date that the licensee permits, pursuant to this section, the individual to work as an authorized nuclear pharmacist.

(c) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity

in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

(d) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

§32.73 [Removed]

8. Section 32.73 is removed.

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

9. The authority citation for part 35 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

10. In § 35.2, the definitions of *authorized nuclear pharmacist* and *pharmacist* are added and the definitions of *authorized user*, *medical use*, paragraphs (1)(i), (2)(i), (3)(i), (4)(i), (5)(i), (6)(i), and (6)(ii) of the definition of *misadministration*; and the introductory sentence of the definition of *written directive* are revised to read as follows:

§35.2 Definitions.

Authorized nuclear pharmacist means a pharmacist who is:

(1) Currently board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;

(2) Identified as an authorized nuclear pharmacist on a Commission or Agreement State license that authorizes the use of byproduct material in the practice of nuclear pharmacy; or

(3) Identified as an authorized nuclear pharmacist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in the practice of nuclear pharmacy.

Authorized user means a physician, dentist, or podiatrist who is:

(1) Board certified by at least one of the boards listed in paragraph (a) of §§ 35.910, 35.920, 35.930, 35.940, 35.950, or 35.960;

(2) Identified as an authorized user on a Commission or Agreement State

license that authorizes the medical use of byproduct material; or

(3) Identified as an authorized user on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material.

Medical use means the intentional internal or external administration of byproduct material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

Misadministration means the administration of:

(1) Involving the wrong patient or human research subject, or wrong radiopharmaceutical; or

(2) Involving the wrong patient or human research subject, wrong radiopharmaceutical, or wrong route of administration; or

(3) Involving the wrong patient or human research subject, or wrong treatment site; or

(4) Involving the wrong patient or human research subject, wrong mode of treatment, or wrong treatment site;

(5) Involving the wrong patient or human research subject, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

(6) Involving the wrong patient or human research subject, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(ii) When the dose to the patient or human research subject exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

Pharmacist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

Written directive means an order in writing for a specific patient or human

research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (6) of this definition, containing the following information:

11. Section 35.6 is added to read as follows:

§35.6 Provisions for research involving human subjects.

A licensee may conduct research involving human subjects using byproduct material provided that the research is conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its NRC license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board."

12. Section 35.7 is added to read as follows:

§35.7 FDA, other Federal, and State requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

§35.8 [Amended]

13. In § 35.8, paragraph (b) is revised to read as follows:

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.21, 35.22, 35.23, 35.29, 35.31, 35.50, 35.51, 35.52, 35.53, 35.59, 35.60, 35.61, 35.70, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, 35.647, and 35.980.

14. In § 35.11, paragraph (a) is revised and paragraph (c) is added to read as follows:

§35.11 License required.

(a) A person shall not manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraphs (b) or (c) of this section.

(c) An individual may prepare unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 35.25, unless prohibited by license condition.

15. In § 35.12, paragraph (e) is added to read as follows:

§ 35.12 Application for license, amendment, or renewal.

* * * * *

(e) An applicant that satisfies the requirements specified in 10 CFR 33.13 may apply for a Type A specific license of broad scope.

16. In § 35.13, paragraph (b) is revised to read as follows:

§ 35.13 License amendments.

* * * * *

(b) Before it permits anyone to work as an authorized user or authorized nuclear pharmacist under the license, except an individual who is:

(1) An authorized user certified by the organizations specified in paragraph (a) of §§ 35.910, 35.920, 35.930, 35.940, 35.950, or 35.960;

(2) An authorized nuclear pharmacist certified by the organization specified in paragraph (a) of § 35.980;

(3) Identified as an authorized user or an authorized nuclear pharmacist on a Commission or Agreement State license that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively; or

(4) Identified as an authorized user or an authorized nuclear pharmacist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively.

* * * * *

17. Section 35.14 is revised to read as follows:

§ 35.14 Notifications.

(a) A licensee shall provide to the Commission a copy of the board certification, the license, or the permit for each individual within 30 days of the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to § 35.13(b)(1) through (b)(4).

(b) A licensee shall notify the Commission by letter within 30 days when:

(1) An authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

(2) The licensee's mailing address changes.

(c) The licensee shall mail the documents required in this section to the appropriate address identified in § 30.6 of this chapter.

18. Section 35.15 is added to read as follows:

§ 35.15 Exemptions regarding Type A specific licenses of broad scope.

A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(a) The provisions of § 35.13(b);

(b) The provisions of § 35.13(e) regarding additions to or changes in the areas of use only at the addresses specified in the license;

(c) The provisions of § 35.14(a); and

(d) The provisions of § 35.14(b)(1) for an authorized user or an authorized nuclear pharmacist.

19. In § 35.22, paragraph (b)(2) is revised to read as follows:

§ 35.22 Radiation Safety Committee.

* * * * *

(b) * * *

(2)(i) Review, on the basis of safety and with regard to the training and experience standards in subpart J of this part, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or a teletherapy physicist before submitting a license application or request for amendment or renewal; or

(ii) Review, pursuant to § 35.13(b)(1) through (b)(4), on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist;

* * * * *

20. In § 35.25, paragraph (b) is redesignated as paragraph (c) and a new paragraph (b) is added to read as follows:

§ 35.25 Supervision.

* * * * *

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 35.11(c), shall require the supervising authorized nuclear pharmacist or physician who is an authorized user to:

(1) Instruct the supervised individual in the preparation of byproduct material for medical use and the principles of and procedures for radiation safety and

in the licensee's written quality management program, as appropriate to that individual's use of byproduct material;

(2) Require the supervised individual to follow the instructions given pursuant to paragraph (b)(1) of this section and to comply with the regulations of this chapter and license conditions; and

(3) Periodically review the work of the supervised individual as it pertains to preparing byproduct material for medical use and the records kept to reflect that work.

* * * * *

§ 35.27 [Removed]

21. Section 35.27 is removed.

22. In § 35.32, paragraphs (a)(2) and (b)(1)(i) are revised to read as follows:

§ 35.32 Quality management program.

(a) * * *

(2) That, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

* * * * *

(b) * * *

(1) * * *

(i) A representative sample of patient and human research subject administrations,

* * * * *

23. In § 35.33, paragraphs (a)(2), (a)(3), (a)(4), (b), and (c) are revised to read as follows:

§ 35.33 Notifications, reports, and records of misadministrations.

(a) * * *

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient or the human research subject; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient or the human research subject (or either individual's responsible relative or guardian), and if not, why not, and if the patient or the human research subject (or either individual's responsible relative or guardian) was notified, what information was provided to that individual. The report must not include the patient's or the human research subject's name or other information that could lead to identification of the patient or the human research subject.

(3) The licensee shall notify both the referring physician and the patient or the human research subject (or the patient's or the human research subject's responsible relative or guardian), of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or the human research subject (or either individual's responsible relative or guardian) or that, based on medical judgment, telling the patient or the human research subject (or either individual's responsible relative or guardian) would be harmful to the patient or the human research subject. The licensee is not required to notify the patient or the human research subject (or either individual's responsible relative or guardian) without first consulting the referring physician. If the referring physician or the patient or the human research subject (or the patient's or the human research subject's responsible relative or guardian) cannot be reached within 24 hours, the licensee shall notify the patient or the human research subject (or either individual's responsible relative or guardian) as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient or the human research subject, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the patient or the human research subject (or either individual's responsible relative or guardian) was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient or the human research subject (or either individual's responsible relative or guardian) by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the patient or the human research subject, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient or the human research subject, and the patient's or human research subject's referring physician), the patient's or the human research subject's social security number or identification number if one has been assigned, a brief description of

the misadministration, why it occurred, the effect on the patient or the human research subject, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients or human research subjects (or either individual's responsible relative or guardian).

24. Section 35.49 is revised to read as follows:

§ 35.49 Suppliers for sealed sources or devices for medical use.

A licensee may use for medical use only:

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 CFR part 30 and § 32.74 or the equivalent regulations of an Agreement State; or

(b) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 10 CFR part 30 or the equivalent regulations of an Agreement State.

25. In § 35.50, paragraphs (a), (b)(3), and (e)(2) through (e)(4) are revised to read as follows:

§ 35.50 Possession, use, calibration, and check of dose calibrators.

(a) A licensee shall possess and use a dose calibrator to measure the activity of dosages of photon-emitting radionuclides prior to administration to each patient or human research subject.

(b) * * *

(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between the highest dosage that will be administered to a patient or human research subject and 1.1 megabecquerels (30 microcuries); and

* * * * *

(e) * * *

(2) For paragraph (b)(2) of this section, the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the identity of the individual performing the test.

(3) For paragraph (b)(3) of this section, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the identity of the individual performing the test.

(4) For paragraph (b)(4) of this section, the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured

for each volume measured, the date of the test, and the identity of the individual performing the test.

26. Section 35.52 is added to read as follows:

§ 35.52 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.

(a) This section does not apply to unit dosages of alpha- or beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements.

(b) For other than unit dosages obtained pursuant to paragraph (a) of this section, a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

27. In § 35.53, the section heading and paragraphs (a), (b), (c)(2), and (c)(3) are revised as follows:

§ 35.53 Measurement of dosages of unsealed byproduct material for medical use.

* * * * *

(a) Measure the activity of each dosage of a photon-emitting radionuclide prior to medical use.

(b) Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements;

(c) * * *

(2) Patient's or human research subject's name, and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 1.1 megabecquerels (30 microcuries);

* * * * *

28. In § 35.60, paragraphs (b) and (c) are revised to read as follows:

§ 35.60 Syringe shields and labels.

(b) To identify its contents, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's or the human research subject's name.

(c) A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit and shall require each individual to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient or human research subject.

29. Section 35.75 is revised to read as follows:

§ 35.75 Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.

(a) A licensee may not authorize release from confinement for medical care any patient or human research subject administered a radiopharmaceutical until either:

(1) The measured dose rate from the patient or the human research subject is less than 5 millirems per hour at a distance of one meter; or

(2) The activity in the patient or the human research subject is less than 30 millicuries.

(b) A licensee may not authorize release from confinement for medical care of any patient or human research subject administered a permanent implant until the measured dose rate from the patient or the human research subject is less than 5 millirems per hour at a distance of one meter.

30. Section 35.100 is revised to read as follows:

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies.

A licensee may use for uptake, dilution, or excretion studies any unsealed byproduct material prepared for medical use that is either:

(a) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.920, or an

individual under the supervision of either as specified in § 35.25.

31. Section 35.200 is revised to read as follows:

§ 35.200 Use of unsealed byproduct material for imaging and localization studies.

A licensee may use for imaging and localization studies any unsealed byproduct material prepared for medical use that is either:

(a) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

32. Section 35.300 is revised to read as follows:

§ 35.300 Use of unsealed byproduct material for therapeutic administration.

A licensee may use for therapeutic administration any unsealed byproduct material prepared for medical use that is either:

(a) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

33. In § 35.310, the introductory text of paragraph (a), and paragraphs (a)(1) and (a)(5) are revised to read as follows:

§ 35.310 Safety instruction.

(a) A licensee shall provide radiation safety instruction for all personnel caring for the patient or the human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75 of this chapter. To satisfy this requirement, the instruction must describe the licensee's procedures for:

(1) Patient or human research subject control;

(5) Notification of the Radiation Safety Officer in case of the patient's or the human research subject's death or medical emergency.

34. In § 35.315, the introductory text of paragraph (a), and paragraphs (a)(2), (a)(3), (a)(5), (a)(6), (a)(7), and (b) are revised to read as follows:

§ 35.315 Safety precautions.

(a) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75 of this chapter, a licensee shall:

(2) Post the patient's or the human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room;

(3) Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(5) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste.

(6) Provide the patient or the human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient or the human research subject.

(7) Survey the patient's or the human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters; and

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient or the human research subject dies or has a medical emergency. 35. Section 35.404 is revised to read as follows:

§ 35.404 Release of patients or human research subjects treated with temporary implants.

(a) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The

licensee may not release from confinement for medical care a patient or a human research subject treated by temporary implant until all sources have been removed.

(b) A licensee shall retain a record of patient or human research subject surveys for three years. Each record must include the date of the survey, the name of the patient or the human research subject, the dose rate from the patient or the human research subject expressed as millirem per hour and measured at one meter from the patient or the human research subject, the survey instrument used, and the initials of the individual who made the survey.

36. In § 35.406, paragraphs (a), (b), and (c) are revised to read as follows:

§ 35.406 Brachytherapy sources inventory.

(a) Promptly after removing them from a patient or a human research subject, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.

(b) A licensee shall make a record of brachytherapy source use which must include:

- (1) The names of the individuals permitted to handle the sources;
- (2) The number and activity of sources removed from storage, the patient's or the human research subject's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage;
- (3) The number and activity of sources returned to storage, the patient's or the human research subject's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

(c) Immediately after implanting sources in a patient or a human research subject the licensee shall make a radiation survey of the patient or the human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

37. In § 35.410, the introductory text of paragraph (a), and paragraphs (a)(3) and (a)(5) are revised to read as follows:

§ 35.410 Safety instruction.

(a) The licensee shall provide radiation safety instruction to all personnel caring for the patient or the human research subject undergoing

implant therapy. To satisfy this requirement, the instruction must describe:

(3) Procedures for patient or human research subject control;

(5) Procedures for notification of the Radiation Safety Officer if the patient or the human research subject dies or has a medical emergency.

38. In § 35.415, the introductory text of paragraph (a), and paragraphs (a)(1), (a)(2), (a)(3), (a)(5) and (b) are revised to read as follows:

§ 35.415 Safety precautions.

(a) For each patient or human research subject receiving implant therapy, a licensee shall:

- (1) Not quarter the patient or the human research subject in the same room with an individual who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirements of § 20.105(b) or, for licensees implementing the provisions of §§ 20.1001 through 20.2401, § 20.1301(a) of this chapter at a distance of one meter from the implant;
- (2) Post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;
- (3) Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer; and
- (5) Provide the patient or the human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before releasing the individual if the individual was administered a permanent implant.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient or the human research subject dies or has a medical emergency.

39. In § 35.610, paragraph (a)(1) is revised to read as follows:

(a) The procedure to be followed to ensure that only the patient or the human research subject is in the treatment room before turning the primary beam of radiation on to begin

a treatment or after a door interlock interruption;

40. In § 35.615, paragraphs (d)(3) and (e) are revised to read as follows:

§ 35.615 Safety precautions.

(3) A radiation monitor must be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

(e) A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or the human research subject from the teletherapy unit console during irradiation.

41. In § 35.900, paragraphs (a)(6) and (a)(7) are added to read as follows:

§ 35.900 Radiation Safety Officer.

- (6) American Board of Medical Physics in radiation oncology physics; or
- (7) Royal College of Physicians and Surgeons of Canada in Nuclear Medicine; or

42. In § 35.910, paragraph (a)(4) is added and paragraphs (b)(2)(i), (b)(2)(iii), and (b)(2)(v) are revised to read as follows:

§ 35.910 Training for uptake, dilution, and excretion studies.

- (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
- (2) (i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
- (iii) Administering dosages to patients or human research subjects and using syringe radiation shields;

(v) Patient or human research subject followup; or

43. In § 35.920, paragraph (a)(4) is added and paragraphs (b)(2)(iii), (b)(3)(i), (b)(3)(iii), and (b)(3)(v) are revised to read as follows:

(v) Patient or human research subject followup; or

43. In § 35.920, paragraph (a)(4) is added and paragraphs (b)(2)(iii), (b)(3)(i), (b)(3)(iii), and (b)(3)(v) are revised to read as follows:

§ 35.920 Training for imaging and localization studies.

- (a) * * *
- (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
- (b) * * *
- (2) * * *
- (iii) Calculating and safely preparing patient or human research subject dosages;
- * * * * *
- (3) * * *
- (i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
- * * * * *
- (iii) Administering dosages to patients or human research subjects and using syringe radiation shields;
- * * * * *
- (v) Patient or human research subject followup; or
- * * * * *
44. In § 35.930, the section heading and paragraph (a)(2) are revised to read as follows:

§ 35.930 Training for therapeutic use of unsealed byproduct material.

* * * * *

(a) * * *

(2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; or

* * * * *

45. In § 35.940, paragraph (a)(1) is revised to read as follows:

§ 35.940 Training for use of brachytherapy sources.

* * * * *

(a) * * *

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

* * * * *

46. In § 35.950, paragraph (a)(1) is revised and (a)(4) is added to read as follows:

§ 35.950 Training for use of sealed sources for diagnosis.

* * * * *

(a) * * *

(1) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

* * * * *

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

* * * * *

47. In § 35.960, paragraphs (a)(1) and (b)(3)(iii) are revised to read as follows:

§ 35.960 Training for teletherapy.

* * * * *

(a) * * *

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(b) * * *

(3) * * *

(iii) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

* * * * *

48. In § 35.961, paragraph (b) is redesignated as paragraph (c) and a new paragraph (b) is added to read as follows:

- (a) * * *
- (1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;
- (b) * * *
- (3) * * *
- (iii) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and
- * * * * *
48. In § 35.961, paragraph (b) is redesignated as paragraph (c) and a new paragraph (b) is added to read as follows:

§ 35.961 Training for teletherapy physicist.

* * * * *

(b) Is certified by the American Board of Medical Physics in radiation oncology physics; or

* * * * *

49. Section 35.972 is revised to read as follows:

§ 35.972 Recentness of training.

The training and experience specified in this subpart must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

50. Section 35.980 is added to subpart J to read as follows:

§ 35.980 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(a) Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) Didactic training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised experience in a nuclear pharmacy involving the following:

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of dose calibrators,

- survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
- (C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
- (D) Using administrative controls to avoid mistakes in the administration of byproduct material;
- (E) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and
- (2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Dated at Rockville, Maryland, this 10th day of June, 1993.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 218

RIN 1010-AB83

Interest Rate Applicable to Late Payment or Underpayment of Monies Due on Solid Minerals and Geothermal Leases

AGENCY: Minerals Management Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Minerals Management Service (MMS) is proposing to amend its Royalty Management Program (RMP) regulations governing the rate of interest charged to lessees and other royalty payors on late or underpayment of monies due to the Federal Government on solid minerals and geothermal leases. This amendment would provide consistency between all mineral leases since the same interest rate will be used for late or underpayment of monies due for all mineral leases. The interest rate used for solid minerals and geothermal leases is currently prescribed by the Department of the Treasury (Treasury) as the "Treasury Current Value of Funds Rate" and would be changed to reference section 6621 of the Internal Revenue Code of 1954 for the applicable interest rate.

DATES: Written comments must be received on or before August 16, 1993.